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No. 08-

IN THE

Supreme Court of the United States

TRI-UNION SEAFOODS, L.L.C.
D/B/A CHICKEN OF THE SEA,
Petitioner,

v.

DEBORAH FELLNER,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether state-law tort claims based upon failure to warn of the risks of methylmercury in tuna fish products are preempted by the Federal Food, Drug, and Cosmetics Act and regulatory actions of the Food and Drug Administration, including a written determination that state-law warning requirements concerning methylmercury in tuna products are preempted by federal law and denial of a petition to require such warnings.

2. Whether a "presumption against preemption" applies in conflict preemption cases.

PARTIES TO THE PROCEEDING AND RULE 29.6 DISCLOSURE

The parties to the proceeding are as follows: Petitioner Tri-Union Seafoods, L.L.C., d/b/a Chicken of the Sea International, was the defendant in the district court and the appellee in the court of appeals. Respondent Deborah Fellner was the plaintiff in the district court and the appellant in the court of appeals.

Tri-Union Seafoods, L.L.C., d/b/a Chicken of the Sea International, is a California limited liability company. Tri-Union Seafoods, L.L.C. is a wholly owned subsidiary of Thai Union International, Inc., a California corporation that has not issued shares or securities that are publicly traded. No publicly owned company owns ten percent or more of the stock of Thai Union International, Inc.

TABLE OF CONTENTS

Page

QUESTIONS PRESENTED i

PARTIES TO THE PROCEEDING AND RULE 29.6 DISCLOSURE ii

TABLE OF AUTHORITIES v

OPINIONS BELOW 1

JURISDICTION 1

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED 1

STATEMENT 2

REASONS FOR GRANTING THE WRIT 15

I. The Court Of Appeals' Decision Conflicts With A California Supreme Court Decision Holding That Similar Agency Actions Are Sufficient To Preempt State Law 16

II. The Court Of Appeals' Decision Allows Manufacturers To Be Held Liable For Failing To Include A Label Warning That Would Violate Federal Law 22

III. The Court of Appeals' Decision Conflicts With Other Courts On The Application Of A Presumption Against Preemption In Conflict Preemption Cases. 27

A. The Court Of Appeals' Decision Conflicts With Decisions Of Other Circuits. 29

B. A Presumption Against Preemption In Conflict Cases Is Contrary To This Court's Recent Practice. 31

CONCLUSION 36

APPENDIX

Court of Appeals Opinion, *Fellner* v. *Tri-Union Seafoods, L.L.C.*, 539 F.3d 237 (3d Cir. 2008) 1a

District Court Opinion, *Fellner* v. *Tri-Union Seafoods, L.L.C.*, (D.N.J. Jan. 8, 2007) 38a

Order Denying Petition For Rehearing En Banc (3d Cir. Sept. 15, 2008) 55a

Relevant Provisions Of The Food and Drug Act 57a

TABLE OF AUTHORITIES

CASES

Page

Allis-Chalmers Corp. v. *Lueck*,
471 U.S. 202 (1985) 32

Altria Group, Inc. v. *Good*,
29 S.Ct. 538 (2008) 14, 33, 34

Arkansas Elec. Coop. v. *Arkansas P.S.C.*,
461 U.S. 375 (1983) 20

Auer v. *Robbins*, 519 U.S. 452 (1997) 20

Bates v. *Dow Agrosciences, LLC*,
544 U.S. 431 (2005) 31, 33

Brown v. *Hotel & Rest. Employees & Bartenders Int'l Union Local 54*,
468 U.S. 491 (1984) 32

Buckman Co. v. *Plaintiffs' Legal Comm.*,
531 U.S. 341 (2001) 28

California v. *ARC American Corp.*,
490 U.S. 93 (1989) 32

Capital Cities Cable, Inc. v. *Crisp*, 467 U.S.
691 (1984) 32

Cipollone v. *Liggett Group, Inc.*,
505 U.S. 504 (1992) 24, 31, 34

Colacicco v. *Apotex, Inc.*,
521 F.3d 253 (3d Cir. 2008) 14, 18, 27

Crosby v. *Nat'l Foreign Trade Council*,
530 U.S. 363 (2000) 31, 33

Dowhal v. *SmithKline Beecham Consumer Healthcare*, 88 P.3d 1 (2004) 17, 18

English v. *Gen. Elec. Co.*, 496 U.S. 72 (1990) 27, 31

Felder v. *Casey*, 487 U.S. 131 (1988) 30

Florida State Conference of the NAACP v. *Browning*, 522 F.3d 1153 (11th Cir. 2008) 29, 30

Forest Park II v. *Hadley*, 336 F.3d 724 (8th Cir. 2003) 28

Freightliner Corp. v. *Myrick*, 514 U.S. 280 (1995) 32

Gade v. *Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88 (1992) 32

Geier v. *Honda Motor Co.*, 529 U.S. 861 (2000) ..... *passim*

Gentry v. *Volkswagen of Am., Inc.*, 521 S.E.2d 13 (Ga. App. 1999) 30

Good v. *Altria Group*, 501 F.3d 29 (1st Cir. 2007) 14

Grocery Manufacturers of America, Inc. v. *Gerace*, 755 F.2d 993 (2d Cir. 1985) 25

Hillsborough County v. *Automated Med. Labs., Inc.*, 471 U.S. 707 (1985) 31, 32

Hines v. *Davidowitz*, 312 U.S. 52 (1941) 27

Int'l Paper Co. v. *Ouellette*, 479 U.S. 481 (1987) 32

Irving v. *Mazda Motor Corp.*, 136 F.3d 764 (11th Cir. 1998) 29, 30

Jones v. *Rath Packing Co.*,
430 U.S. 519 (1977) 32

Lewis v. *Brunswick Corp.*,
107 F.3d 1494 (11th Cir. 1997) 29

La. Pub. Serv. Comm'n v. *FCC*,
476 U.S. 355 (1986) 32

Masterson v. *Apotex Corp.*, 2008 U.S. Dist.
LEXIS 60238 (S.D. Fla. Aug. 7, 2008) 30

Medtronic v. *Lohr*, 518 U.S. 470 (1996) 27, 31, 34

Nathan Kimmel, Inc. v. *DowElanco*,
275 F.3d 1199 (9th Cir. 2002) 28

New York v. *FCC*, 486 U.S. 57 (1988) 13, 18

Perry v. *Mercedes Benz N. Am., Inc.*, 957
F.2d 1257 (5th Cir. 1992) 30

Rice v. *Santa Fe Elevator Corp.*,
331 U.S. 218 (1947) 33, 34

Riegel v. *Medtronic, Inc.*,
128 S. Ct. 999 (2008) 24

Silkwood v. *Kerr-McGee Corp.*,
464 U.S. 238 (1984) 31

Sprietsma v. *Mercury Marine*,
537 U.S. 51 (2002) 14, 20, 21, 31, 33

Taylor v. *General Motors Corp.*,
875 F.2d 816 (11th Cir. 1989) 29

United States v. *Locke*, 529 U.S. 89 (2000) 31, 33

*Wis. Dep't of Indus., Labor & Human
Relations* v. *Gould Inc.*, 475 U.S. 282
(1986) 32

STATUTES & REGULATORY MATERIALS

21 U.S.C. § 301 2

21 U.S.C. § 343 2

21 U.S.C. § 321 2

21 C.F.R. § 10.30 7

21 C.F.R. § 10.33 7

21 C.F.R. § 10.35 7

21 C.F.R. § 101.17 3

21 C.F.R. § 172.804 3

Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353..... 4

42 Fed. Reg. 52,814 (Sept. 30, 1977) 2

44 Fed. Reg. 3,990 (Jan. 19, 1979)..... 4, 22

44 Fed. Reg. 59,509 (Oct. 16, 1979) 3

63 Fed. Reg. 37,030 (July 8, 1998)..... 3

Cal. Health & Saf. Code § 25249.6 9

Cal. Health & Saf. Code § 25249.10 9

N.J.S.A. 2A:58C-1..... 11

N.J.S.A. 56:8-1..... 11

OPINIONS BELOW

The opinion of the court of appeals, App., *infra*, 1a-37a, is reported at 539 F.3d 237. The opinion of the district court, App., *infra*, 38a-54a, is unreported.

JURISDICTION

The judgment of the court of appeals was entered on August 19, 2008. App., *infra*, 1a. The court of appeals denied a petition for rehearing on September 15, 2008. *Id.* at 55a-56a. On December 5, 2008, Justice Souter extended the time to file a petition for a writ of certiorari to January 13, 2009. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Supremacy Clause of the United States Constitution provides, in relevant part:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const. Art. VI.

Relevant provisions of the Food, Drug, and Cosmetics Act, 21 U.S.C. § 301 *et seq.*, are reprinted in the Appendix. App., *infra*, 57a-62a.

STATEMENT

1. FDA's Regulation Of Food Safety. Congress has entrusted the Food and Drug Administration ("FDA") with responsibility to protect the safety of food products in the United States. *See* Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 *et. seq.* Under the FDCA, FDA has broad authority to regulate the labels of food products. *See* 21 U.S.C. § 343 *et seq.* In addition, the FDCA prohibits the transmission in interstate commerce of food that is adulterated or misbranded and authorizes FDA to enforce those prohibitions. *See* 21 U.S.C. §§ 343(a)(1) & 321(n).

FDA's basic approach to regulating food safety is to (1) prohibit the marketing of foods that may pose health risks and (2) develop tolerance and "action" levels to limit the amount of potentially dangerous substances in foods. *See, e.g.*, 42 Fed. Reg. 52,814 (Sept. 30, 1977). If foods exceed tolerance or action levels established by FDA, the agency may find that they are "adulterated" in violation of the FDCA.

In exercising its authority to regulate food labeling, FDA has opted not to require warnings for every ingredient or product that has possible deleterious effects. Instead, FDA relies primarily on disclosure of ingredient and nutrition information on food labels and directs manufacturers to provide warnings on labels only in exceptional

circumstances.[1] FDA has adopted this regulatory approach to avoid overexposing consumers to warnings, which could confuse consumers or cause them to ignore all such statements. *See, e.g.*, 63 Fed. Reg. 37,030, 37,035 (July 8, 1998) (concluding that "too many warning labels on foods could result in loss of consumer credibility and effectiveness"); 44 Fed. Reg. 59,509, 59,513 (Oct. 16, 1979) ("A requirement for warnings on all foods that may contain an inherent carcinogenic ingredient or a carcinogenic contaminant . . . would apply to many, perhaps most foods in a supermarket. Such warnings would be so numerous they would confuse the public, would not promote informed consumer decisionmaking, and would not advance the public health.").

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[1] For example, FDA requires that any food containing the sweetener aspartame must include the following statement on the label: "Phenylketonurics: contains phenylalanine." 21 C.F.R. § 172.804(d)(2). Juices that have not been pasteurized must include the following statement on the label: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious injury in children, the elderly, and persons with weakened immune systems." 21 C.F.R. § 101.17(g). Food products that derive more than 50 percent of their total caloric value from whole protein, protein hydrolysates, amino acid mixtures, or a combination of these, and are represented for use in weight reduction, must include the following statement on the label: "WARNING: Very low calorie protein diets (below 400 Calories per day) may cause serious illness or death. Do Not Use for Weight Reduction in Such Diets Without Medical Supervision. Not for use by infants, children, or pregnant or nursing women." 21 C.F.R. § 101.17(d).

In 1990, Congress amended the FDCA to expressly preempt certain state requirements concerning nutrition labeling, food standards of identity, and other label requirements. Nutrition Labeling and Education Act of 1990 ("NLEA"), Pub. L. No. 101-535, 104 Stat. 2353, 2364. Section 6(c) of the NLEA, entitled "Construction," provides that the express preemption provisions should not be construed to preempt state food warning requirements, but that nothing in the 1990 amendments should be construed to affect preemption, "express or implied," of any state requirement under the Constitution, any provision of the FDCA not amended by the NLEA, or any other federal law. 104 Stat. at 2364.

2. FDA's Regulation Of Methylmercury In Fish. FDA has studied the risks of methylmercury in fish for decades. In 1979, FDA determined that a methylmercury action level of 1.0 part per million is safe for seafood. 44 Fed. Reg. 3,990, 3,993 (Jan. 19, 1979). In the ensuing decades, FDA has engaged in an extensive program to evaluate the risks of mercury in fish. Based on this evaluation, FDA has taken a series of regulatory actions, including: (1) issuing consumer advisories targeted at vulnerable subpopulations concerning the risks of methylmercury in fish, (2) rejecting a petition to require product-label warnings about the risks of mercury in fish, and (3) issuing a written determination that state-law warning requirements concerning the risks of mercury in tuna are preempted by federal law.

a. *FDA's Consumer Advisories.* FDA first issued an advisory on methylmercury in fish in 1995. The 1995 Advisory, entitled "Is Mercury in Fish a Safety Concern?," stated: "FDA food specialists say that eating a variety of types of fish, the normal pattern of consumption, does not put anyone in danger of mercury poisoning. It is when people eat fad diets—frequently eating only one type of food or a particular species of fish—that they put themselves at risk." C.A. App. A155. The 1995 Advisory stated that "consumption advice is unnecessary for the top 10 seafood species," including "canned tuna." *Id.*

The current Advisory, entitled "What You Need to Know About Mercury in Fish and Shellfish," was issued jointly by FDA and the Environmental Protection Agency ("EPA") in 2004. EPA-823-R-04-005, http://www.cfsan.fda.gov/~dms/admehg3.html (March, 2004) ("2004 Advisory"). The 2004 Advisory states that "[f]ish and shellfish are an important part of a healthy diet." *Id.* They "contain high-quality protein and other essential nutrients, are low in saturated fat, and contain omega-3 fatty acids." Because "[a] well-balanced diet that includes a variety of fish and shellfish can contribute to heart health and children's proper growth and development," FDA and EPA advise that "women and young children in particular should include fish or shellfish in their diets due to the many nutritional benefits." *Id.*

The Advisory further states that "nearly all fish and shellfish contain traces of mercury." FDA and EPA advise that, "[f]or most people, the risk from mercury by eating fish and shellfish is not a

health concern." The agencies note, however, that "some fish and shellfish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system." *Id.*

FDA and EPA make three principal recommendations for women and young children:

> (1) Do not eat certain fish that contain high levels of mercury (shark, swordfish, king mackerel, and tilefish);
>
> (2) Eat up to 12 ounces a week of a variety of fish and shellfish that are lower in mercury (including canned light tuna), or up to 6 ounces per week of albacore tuna; and
>
> (3) Check local advisories concerning the safety of fish caught by family and friends in local waters, and if no advice is available eat up to 6 ounces per week of fish you catch from local waters.

b. *FDA's Denial of the Martek Petition.* In September 2004, FDA issued a decision allowing qualified health claims that "[s]upportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease."[2] In deciding to allow such

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[2] Letter from William K. Hubbard, Assoc. Comm'r for Policy & Planning, FDA, to Martin J. Hahn, Hogan & Hartson, LLP (Sept. 8, 2004), http://www.fda.gov/ohrms/dockets/dockets/03q0401/03q-0401-ans0002-vol13.pdf ["FDA Martek Petition (continued...)

claims, FDA considered and rejected a petition filed by Martek Biosciences Corporation ("Martek") seeking to require that any qualified health claim concerning fish products, including tuna products, should be accompanied by an advisory statement recommending a limited weekly intake for a vulnerable population of pregnant women, women of childbearing age, nursing mothers, and young children.

The Martek Petition was submitted in accordance with FDA's regulations regarding petitions by interested persons, codified at 21 C.F.R. §§ 10.30, 10.33, 10.35, and with FDA's interim procedures for qualified health claims. FDA Martek Petition Denial at 1-2 & n.1. Those procedures include notice and opportunity for public comment, scientific review, consultation with other federal agencies, the issuance of a written regulatory decision, and the possibility of agency reconsideration. FDA Center for Food Safety & Applied Nutrition, Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements, http://www.cfsan.fda.gov/~dms/hclmgui3.html. In response to the Martek Petition, FDA received and considered comments from "industry, a professional organization, and an individual." FDA Martek Petition Denial at 2.

Denial"]; Letter from William K. Hubbard, Assoc. Comm'r for Policy & Planning, FDA, to Jonathan W. Emord, Emord & Associates, PC (Sept. 8, 2004), http://www.fda.gov/ohrms/dockets/dockets/03q0401/03q-0401-ans0001-vol13.pdf.

In denying the Martek Petition, FDA explained that because of limited space, a warning label could not provide the "level of clarity and detail" in FDA's advisory statements. *Id.* at 29. In addition, FDA noted, different labels in line with FDA guidance regarding particular fish species and locally caught versus commercially raised fish could cause consumer confusion. *Id.* Moreover, FDA research suggests that "a label statement that reaches the public at large can also have unintended adverse public health consequences" due to deterring people outside the target groups from eating any fish at all. *Id.* The agency stated:

> FDA disagrees with the petitioners' contention that the omega-3 fatty acid qualified health claim should be accompanied by a product label statement about mercury content of fish and possible harmful health effects to the vulnerable population of pregnant women, women who might become pregnant, nursing mothers, and young children. For some time, FDA has been addressing the issue of reducing the exposure to the harmful effects of mercury by communicating with the target population . . . through the use of consumer advisories. . . .

Id. at 28. The agency concluded, *"FDA has decided that it is preferable not to use a label statement about mercury."* *Id.* at 29 (emphasis added).

c. *FDA's Preemption Letter.* In August 2005, the Commissioner of the FDA issued a letter to the California Attorney General concerning warning labels on tuna products in response to litigation brought by the Attorney General of California under California's Proposition 65.[3] Letter to Bill Lockyer, Attorney General of the State of California, http://www.cfsan.fda.gov/~dms/fl-ltr65.html. The letter explains that, after analyzing the research on methylmercury in tuna, FDA has adopted and implemented a regulatory approach that is intended to balance the health benefits of consuming fish against the potential risks to a subpopulation that includes pregnant women, women who may become pregnant, nursing mothers, and young children.

The FDA letter explains that, "rather than requiring warnings for every single ingredient or product with possible deleterious effects, FDA has deliberately implemented a more nuanced approach, relying primarily on disclosure of ingredient information and nutrition information. . . ." *Id.* FDA has required warnings "only in those instances where there is clear evidence of a hazard, in order to avoid overexposing consumers to warnings, which could result in them ignoring all such statements,

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[3] Proposition 65 provides that "[n]o person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual." Cal. Health & Saf. Code § 25249.6. Proposition 65 does not apply to "[a]n exposure for which federal law governs warning in a manner that preempts state authority." Cal. Health & Saf. Code § 25249.16

and hence creating a far greater public health concern." *Id.*

The FDA Commissioner explained the reasons for FDA's regulatory decision to issue consumer advisories rather than requiring warnings on product labels:

> First, consumer advisories are communicated to the target audience directly, rather than to all consumers. Second, FDA believes that the advisory approach is more effective than a product label statement in relaying the complex messages about mercury in seafood. Third, a label statement that reaches the public at large can also have unintended adverse public health consequences. FDA focus group results have suggested that people who are not in the target audience might eat less fish or refrain from eating fish altogether when they receive information about the mercury content of fish and possible harmful health effects to the targeted audience.

Id. The FDA letter noted that these same concerns led it to reject the Martek petition's proposal that a mercury warning should accompany qualified health claims about omega-3 fatty acids. *Id.* For these reasons, FDA concluded that it would be impossible to comply with state law requiring a warning on the product label concerning methylmercury in fish and

at the same time comply with FDA's regulatory requirements. *Id.*

3. This Case. Respondent brought this action against Petitioner in New Jersey state court seeking damages for harm she allegedly sustained as a result of consuming tuna fish. She alleges that from 1999 to 2004, her diet consisted almost exclusively of Chicken-of-the-Sea tuna fish products. She further alleges that, as a result of her consumption of tuna fish, she suffered injuries from mercury poisoning. Respondent asserts her claim that Petitioner failed to warn of the risks of consuming tuna fish under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 *et seq.*, the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq.*, and common law fraud. App., *infra*, 38a-39a. After removing the case to federal court (based upon diversity of citizenship), Petitioner filed a motion to dismiss for failure to state a claim, contending that Respondent's state-law failure-to-warn claim is preempted by federal law.

4. The District Court's Decision. The district court (D.N.J., Cavanaugh, J.) granted Petitioner's motion to dismiss. App., *infra*, 38a-54a. The court concluded that there is "a pervasive federal regulatory scheme implemented by and through the FDA." App., *infra*, 44a. The court cited FDA's determination that additional warnings concerning the risks of methylmercury in tuna fish products required under California law would "frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish." App.,

infra, 45a (quoting FDA letter at 1). The court explained that FDA, after many years of study, "has chosen to issue an advisory rather than to require a warning on fish and shellfish labels for several reasons." *Id.* (quoting FDA letter at 2). The court further observed that FDA's Consumer Advisory "specifically rejected the notion that warning labels should be included on cans of tuna." *Id.*

The district court framed the "essential issue" as "whether the FDA's regulatory scheme as explained and embodied in the FDA Letter, Advisory and other materials is entitled to deference from this Court." App., *infra*, 47a. The court rejected Respondent's argument that the FDA letter is not entitled to judicial deference because it is "too informal" and "appears to have been solicited for the express purpose of derailing litigation against [Petitioner] and other seafood companies." *Id.* The court noted that "it is not uncommon for the FDA to specifically choose the issuance of an advisory rather than an official warning." *Id.* at 50a. Moreover, the court reasoned, courts do not require "'a specific formal agency statement identifying conflict in order to conclude that such a conflict in fact exists.'" *Id.* (quoting *Geier* v. *Honda Motor Co.*, 529 U.S. 861, 884-85 (2000)).

The court found that FDA's Consumer Advisory and an accompanying Backgrounder, which were released before litigation began, "evidence a clear effort by the FDA and EPA to encourage the continued public consumption of fish." App., *infra*, 49a. The FDA letter "only crystallizes the already transparent intent of the FDA to preempt state law

that might interfere with the FDA's concern that warnings on tuna products may upset the desired balance between informing consumers of both the benefits and risks of fish consumption." *Id.* at 51a.

The district court declined to "turn a blind eye to the evidence of the FDA's ten-year deliberately balanced approach to the issue of methylmercury in fish." *Id.* at 53a. Because "it would be impossible for [Petitioner] to comply with the FDA and New Jersey law," the court granted Petitioner's motion to dismiss.[4] *Id.* at 52a.

5. The Court Of Appeals' Decision. The court of appeals (Sloviter, Smith & Stapleton, JJ.), reversed. The appellate court recognized that "federal regulations as well as statutes can establish federal law having preemptive force." App., *infra*, 9a (citing *New York* v. *FCC*, 486 U.S. 57, 63 (1988)). The court also recognized that, "in appropriate circumstances, federal agency action taken pursuant to statutorily granted authority" may have preemptive effect outside the context of notice-and-comment rulemaking. *Id.* For example, the court of appeals has held that state-law claims against drug manufacturers for failing to warn that certain prescription drugs created an increased risk of suicidality are preempted, based upon FDA's approval of the drugs' labeling both at the time the drugs were first marketed and thereafter. *Id.* (citing

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[4] The district court dismissed plaintiffs' common law fraud claim on the ground that it violated New Jersey's "single cause of action rule." App., *infra*, 54a.

Colacicco v. *Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008)).[5] In *Colacicco*, the court determined that FDA had "'clearly and publicly stated its position [regarding the propriety of the warning in the pertinent circumstances] prior to the prescriptions and deaths at issue.'" App., *infra*, 11a (quoting *Colacicco*, 521 F.3d at 271 (bracketed text in original)). FDA's actions, the *Colacicco* court held, "established a policy against the sought-after warnings applicable not only to the immediate participants but also to others in like circumstances." App., *infra*, 11a.

The court of appeals observed that a federal agency's decision not to regulate will not preempt state law absent an "'authoritative message of federal policy'" that an issue is to remain free of state regulation. *Id.* at 16a (quoting *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 67 (2002)). The court concluded that FDA's actions in this case were "less formal" than the agency's actions in *Colacicco*, and for that reason do not preempt state law. The court stated that it had "found no case in which a letter that was not the product of some form of agency proceeding and did not purport to impose new legal obligations on anyone was held to create federal law capable of preemption." App., *infra*, 13a.

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[5] The court of appeals disagreed with suggestions by some courts that notice-and-comment rulemaking is the only type of federal agency action that can preempt state law. App., *infra*, 9a (citing *Good* v. *Altria Group*, 501 F.3d 29, 51-52 (1st Cir. 2007), *aff'd on other grounds*, 129 S. Ct. 538 (2008)).

The court of appeals declined to defer to FDA's Advisory and Backgrounder on the ground that they "are not agency interpretations of regulations claimed to preempt state law but rather are the very agency actions which are claimed to preempt state law." *Id.* at 23a. The court acknowledged that the Commissioner's letter is entitled to "consideration" under *Geier*, but stated that "we do not find the letter persuasive" because the views expressed in the letter "have not been shown to be the product of any agency proceeding," "were not expressed at the time" the agency took the actions at issue or when Respondent's damages allegedly arose, and are "not self-evident from the nature of the actions themselves." *Id.* at 23a-24a.

In reversing the district court, the court of appeals applied a "presumption against preemption." *Id.* at 18a-21a. In the court's view, "a state tort-like action seeking damages for an alleged failure to warn consumers of dangers arising from the use of a product" is "squarely within the realm of traditional state regulation." *Id.* at 19a-20a. The court of appeals acknowledged that "the Supreme Court has applied the presumption in few conflict preemption cases of late," but stated that it will continue to apply the presumption "until the Supreme Court provides guidance to the contrary." *Id.* at 21a.

REASONS FOR GRANTING THE WRIT

The court of appeals' holding that FDA's regulatory actions with respect to mercury in fish products were not sufficiently formal to preempt state law merits further review for three reasons.

First, the decision conflicts with a decision of the California Supreme Court according preemptive force to similar FDA actions. The court of appeals' refusal to defer to FDA's regulatory actions embodied in its Consumer Advisories, the denial of the Martek Petition, and the FDA letter to the California Attorney General is also inconsistent with this Court's precedent, which recognizes that agency action need not rise to the level of formality that attends notice and comment procedures to carry preemptive force. Moreover, the court of appeals disregarded the Martek petition, which was the subject of public notice and comment.

Second, the court of appeals has placed Petitioner in an untenable position by subjecting it to potential liability under state law for failing to include a warning label that in FDA's view would render its products misbranded under federal law.

Third, the court of appeals' reliance on a presumption against preemption conflicts with the decisions of other federal courts of appeals, which have rejected the presumption in conflict preemption cases.

I. The Court Of Appeals' Decision Conflicts With A California Supreme Court Decision Holding That Similar Agency Actions Are Sufficient To Preempt State Law.

The court of appeals' decision conflicts with a decision of the California Supreme Court holding that similar FDA actions are sufficient to preempt state law. In *Dowhal* v. *SmithKline Beecham*

Consumer Healthcare, 88 P.3d 1 (2004), the California Supreme Court unanimously held that federal law preempts California's Proposition 65, to the extent that the state law mandates the placement of warnings on products containing nicotine sold over the counter as aids to stop smoking. The California Supreme Court concluded that an FDA letter "established a federal policy prohibiting defendants from giving consumers any warning other than the one approved by the FDA in that letter." *Id.* at 11. FDA's letter established a federal policy directed towards a "nuanced goal – to inform pregnant women of the risks of [Nicotine Replacement Therapy] products, but in a way that will not lead some women, overly concerned about those risks, to continue smoking." *Id.* at 15. The court held that this federal policy "creates a conflict with the state's more single-minded goal of informing the consumer of the risks," and therefore held the state law preempted. *Id.*

In reaching that conclusion, the California Supreme Court expressly rejected plaintiff's argument that "the FDA action is not sufficiently definite and authoritative to create a conflict with state law." *Id.* at 9. The court held that, although FDA's letter "did not expressly reject all possible Proposition 65 warnings," it "announced . . . that the FDA had developed 'a uniform warning that manufacturers . . . will be requested to implement.'" *Id.* at 10 (quoting FDA letter at 5). The court also rejected the plaintiff's argument that FDA's letter should not be considered authoritative because it "has not been published in the Federal Register." *Id.* The Court concluded: "There is no requirement . . .

that it be so published to be effective." *Id.* The California Supreme Court observed that this Court's decision in *Geier*, 529 U.S. at 883-84, rejected "a contention that formal notice-and-comment rulemaking should be required before an agency's action has preemptive force," and "found federal policy to be sufficiently definite as to create a conflict when that policy was set out only in comments of the Department of Transportation accompanying its revision of the airbag rules and in statements in the Solicitor General's brief submitted on the agency's behalf." *Dowhal*, 88 P.3d at 10.

In this case, the court of appeals acknowledged this Court's decisions holding that federal regulations, as well as federal statutes, can preempt state law. App., *infra*, 9a (citing *New York* v. *FCC*, 486 U.S. at 63). It also recognized that notice-and-comment rulemaking is not the only type of agency action that can preempt state law. *Id.* (citing *Colacicco*, 521 F.3d at 271); *see Geier*, 529 U.S. at 883-84. "It is clear, for example, that federal agency orders resulting from quasi-judicial agency proceedings may constitute 'federal law' under the Supremacy Clause." App., *infra*, 9a-10a (citations omitted). Such proceedings may establish a policy that is "applicable not only to the immediate participants but also to others in like circumstances, such as the defendants." *Id.* at 11a.

Yet the court of appeals held that neither FDA's letter nor its other regulatory actions concerning methylmercury in tuna is sufficient to "create federal law capable of preemption." App., *infra*, 13a. In *Dowhal*, in contrast, the California

Supreme Court held that an FDA letter *did* adopt a federal policy that preempted conflicting state law, and specifically rejected arguments that the letter was not sufficiently authoritative or definite to have preemptive effect.[6]

Although the court of appeals did not cite or discuss the California Supreme Court's decision in *Dowhal*, it stated that it had "found no case in which a letter that was not the product of some form of agency proceeding and did not purport to impose new obligations on anyone was held to create federal law capable of preemption." App., *infra*, 13a. The California Supreme Court's opinion in *Dowhal* does not hold or even suggest that these were critical elements of its decision. Moreover, the FDA's letter denying the Martek Petition (which is quoted and discussed in FDA's letter to the California Attorney General) *was* the product of an agency proceeding, initiated by Martek's petition to require that any qualified health claims for omega-3 fatty acids be accompanied by a warning about the risks of mercury in fish. In denying that petition following public notice and an opportunity for comment, FDA expressly stated that it "has decided that it is preferable not to use a label statement about mercury." FDA Martek Petition Denial at 29.

The court of appeals nevertheless held that FDA has not made an "authoritative" agency

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[6] Indeed, the letter at issue in this case was signed by the head of FDA, while the letter at issue in *Dowhal* was signed by a subordinate FDA official.

determination that the issue of mercury in fish products shall be left unregulated. *Id.* at 15a (citing *Sprietsma*, 537 U.S. at 67). As in *Dowhal*, however, FDA's letter sets forth a considered determination that a warning concerning the risks of mercury in tuna should not be included on the product label. FDA did not simply conclude that it would not require such a label, but that the likely risks to health associated with such a warning outweigh the likely benefits. As in *Geier*, FDA "is likely to have a thorough understanding of its own [policy] and its objectives, and is 'uniquely qualified' to comprehend the likely impact of state requirements." 529 U.S. at 883. Moreover, there is "no reason to suspect" that the FDA letter—which sets out the agency's longstanding position that targeted consumer advisories on mercury in fish rather than a general warning on product labels is the regulatory approach that best serves public health—"reflects anything other than 'the agency's fair and considered judgment on the matter.'" *Id.* at 884 (quoting *Auer* v. *Robbins*, 519 U.S. 452, 461-62 (1997)). For these reasons, this case is unlike *Sprietsma*, in which the federal agency made a simple decision not to regulate that stopped short of an "authoritative message" of a federal policy against regulation. 537 U.S. at 67.

The court of appeals relied on language in this Court's opinion in *Sprietsma* that "although the Coast Guard's decision not to require propeller guards was undoubtedly intentional and carefully considered, it does not convey an 'authoritative' message of a federal policy against propeller guards." 537 U.S. at 67 (quoting *Arkansas Elec. Coop.* v.

Arkansas P.S.C., 461 U.S. 375, 384 (1983)). The Third Circuit interpreted this statement as requiring that the federal agency's decision must carry the force of law. App., *infra*, 16a. As explained above, FDA's decision to establish an authoritative policy against mercury warning labels, and its rejection of the Martek Petition following notice and an opportunity for comment, do carry the force of law. But even if that were not so, the Third Circuit's understanding of this Court's opinions is incorrect for several reasons.

First, the term "authoritative" in *Sprietsma* is quoted from the Court's opinion in *Arkansas Electric Coop.*, which stated: "[A] federal decision to forgo regulation in a given area may *imply* an authoritative federal determination that the area is best left unregulated, and in that event would have as much pre-emptive force as a decision to regulate." 461 U.S. at 384 (emphasis added; original emphasis deleted). Given that an authoritative federal determination may be conveyed by implication, it cannot be the case that *Arkansas Electric Co-op.* or *Sprietsma* requires that the agency's determination carry the force of law.

Second, the four-Justice minority in *Geier*, two years earlier, would have required the agency to subject its preemption determination to notice-and-comment rulemaking and publish its determination in the *Federal Register*. *Geier*, 529 U.S. at 911 (Stevens, J., dissenting). It is noteworthy that the Court's decision in *Sprietsma* mentions no such requirements. *Third*, as a practical matter, an

agency's decision *not* to regulate is rarely set forth in a regulation.[7]

Further review is warranted to resolve the conflict with *Dowhal* and to make clear that FDA's authoritative policy against product labels warning about mercury in fish is sufficiently formal to preempt conflicting state law.

II. The Court Of Appeals' Decision Allows Manufacturers To Be Held Liable For Failing To Include A Label Warning That Would Violate Federal Law.

The head of FDA has issued a written determination that adding warnings about the risks of methylmercury to the labels of tuna products would cause the products to be misbranded in violation of Section 403 of the FDCA. FDA determined that the warnings required by California's Proposition 65 would be misleading because they lack a "scientific basis as to the possible

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[7] The court of appeals did not address Respondent's argument—made for the first time on appeal—that the complaint asserts a "design defect" claim that is not preempted. App., *infra*, 3a n.1. Respondent contends that Petitioner's tuna is "unsafe to eat" because it contains methylmercury. Resp. C.A. Br. at 44. Petitioner disagrees that there is any viable "design defect" claim separate from Respondent's failure to warn claim; however, any such claim would be preempted by FDA's regulatory determination that fish with a mercury level of less than 1.0 part per million (like that sold by Petitioner) is safe for consumption, *see* 44 Fed. Reg. at 3,993 (Jan. 19, 1979), and by its considered regulatory decision that warning labels are inappropriate for mercury in tuna.

harm caused by the particular food in question, or as to the amounts of such foods that would be required to cause this harm," and "omit facts which are necessary to place the information in its proper context." FDA letter at 6. Accordingly, FDA determined that "[t]una manufacturers would not be able to comply both with Proposition 65 and the [FDCA]." *Id.*

The court of appeals recognized that "[h]ad the FDA considered the factual basis for the alleged duty to warn and exercised its misbranding authority to establish that a warning based on that data would be false and misleading under federal law—not merely that the FDA had failed to require the warning, but had exercised its authority specifically to reject it" then "a state failure-to-warn lawsuit would be preempted." App., *infra*, 33a-34a. Despite that recognition, the court of appeals concluded that FDA has expressed only an "informal policy opinion in a letter" that is not sufficient to give rise to preemption.

The Third Circuit's reasoning is flawed. As an initial matter, the prohibition on misbranding is imposed directly by the FDCA, not by FDA. Moreover, FDA has expressed more than an "informal . . . opinion" that adding warnings to the labels of tuna products would violate federal law. FDA's letter to the California Attorney General reflects a considered determination that including the warnings required by Proposition 65 on tuna labels would render the product misbranded in violation of the FDCA. In addition, FDA has rejected the Martek Petition, which asked the agency to

require that qualified health claims about fish be accompanied by warnings concerning methylmercury. In denying the Martek Petition, FDA found that product-label warnings are less effective than its advisories because they can confuse consumers and have adverse public health consequences. FDA Martek Petition Denial 28-29.

The court of appeals' decision places tuna manufacturers in a double-bind. If they add warnings about the risks of methylmercury to the labels of tuna products, they subject themselves to liability under federal law. But if they omit such warnings, they risk liability under state tort law. While the court of appeals asserted that "FDA has taken no misbranding action pertaining to the risk of mercury in tuna," App., *infra*, 34a, regulated parties are not permitted to wait for an engraved invitation to comply with federal law. Nor should they be required—on threat of civil damages—to comply with conflicting state obligations until they are directly ordered to do otherwise.[8]

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[8] The Court has recognized that judgments based on state common-law, as well as state statutes, create legal duties that are preempted if they conflict with federal law. *See Riegel* v. *Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008) ("[C]ommon-law liability is 'premised on the existence of a legal duty,' and a tort judgment therefore establishes that the defendant has violated a state-law obligation . . . . And while the common-law remedy is limited to damages, a liability award 'can be, indeed is designed to be, a potent method of governing conduct and controlling policy.'") (quoting *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 521-22 (1992)).

The court of appeals' opinion is in significant conflict with the Second Circuit's decision in *Grocery Manufacturers of America, Inc.* v. *Gerace*, 755 F.2d 993 (2d Cir. 1985). In that case, the Second Circuit held that a New York law requiring that the word "imitation" be used in the labeling of certain cheese products "would render the product misbranded under federal law." *Id.* at 1001. Accordingly, "[c]ompliance with both the state and federal requirements is impossible," and therefore "[t]o the extent that it attempts to regulate the labeling of alternative cheese, the New York law is preempted." *Id.* Here, contrary to the Second Circuit in *Grocery Manufacturers*, the Third Circuit would permit a lawsuit imposing liability for a manufacturer's failure to include a label that FDA has concluded would render the product misbranded.

The court of appeals suggested that Petitioner could satisfy both federal and state requirements by including label warnings that only "frequent tuna consumption" might be harmful, while "moderate fish consumption offers positive health benefits." App., *infra*, 35a. But the court's simplistic formulation does not address FDA's misbranding concerns and fails to take account of the nuanced and detailed content of the FDA Advisory.

Just as with the Proposition 65 warnings addressed in the FDA letter, the vague warning suggested by the court of appeals would be added "without any scientific basis as to the possible harm caused by the particular foods in question, or as to the amounts of such foods that would be required to cause this harm." FDA letter at 6. Consequently,

the court of appeals' suggested warning would be "misleading under section 403 of the Act, causing tuna products with such warnings to be misbranded under federal law." *Id.*

Moreover, the court of appeals' suggested warning ignores the greater part of FDA's message: First, it fails to distinguish the targeted population, pregnant women, women who may become pregnant, nursing mothers, and young children, from other fish consumers. *See* 2004 Advisory, http://www.cfsan.fda.gov/~dms/admehg3.html. Second, it fails to state that women and young children are advised to eat up to 12 ounces (or two average meals) of fish that are low in mercury each week, including canned light tuna. *Id.* Third, it fails to state that, when choosing these two meals, women and children may eat up to 6 ounces per week of albacore tuna, which has more mercury than canned light tuna. *Id.* Fourth, it fails to advise consumers that if they eat fish that is locally caught by family or friends, they should eat only 6 ounces of fish per week. *Id.*

Most fundamentally, the Third Circuit ignored the conflict between a state-law warning requirement and FDA's determination that warnings concerning the risks of mercury in fish are better conveyed through consumer advisories and other means that are directed to the target subpopulation, because label warnings would discourage the general population from consuming fish, and thus have a negative effect on the public health. FDA letter at 6.

III. The Court of Appeals' Decision Conflicts With Other Courts On The Application Of A Presumption Against Preemption In Conflict Preemption Cases.

The court of appeals applied a presumption that Respondent's failure to warn claim is not preempted. App., *infra*, 18a-21a. The court acknowledged that this Court "has applied the presumption in few conflict preemption cases of late," and that "arguments have been raised that the conflict preemption analysis subsumes or supplants the presumption." App., *infra*, 21a (citing *Colacicco*, 521 F.3d at 265). The court nevertheless held that it "will continue to apply the traditional presumption until the Supreme Court provides guidance to the contrary." App., *infra*, 21a.

The court of appeals started from the proposition that such a presumption applies in "all pre-emption cases," including conflict preemption cases. App., *infra*, 18a-19a (quoting *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 485 (1996)).[9] The court stated "that the presumption remains applicable when preemption claims concern areas of the law 'which

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[9] An "actual conflict" between State and Federal law exists "where it is impossible for a private party to comply with both state and federal requirements," or "where state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *English* v. *Gen. Elec. Co.*, 496 U.S. 72, 79 (1990) (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)). There is no "legal wedge" between, and thus "no grounds . . . for attempting to distinguish," these two manifestations of actual conflict. *Geier*, 529 U.S. at 873-74.

the States have traditionally occupied,' but that it may not be applicable 'where the interests at stake are uniquely federal in nature.'" *Id.* at 19a (quoting *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001)). The court concluded that "a state tort-like action seeking damages for an alleged failure to warn" fits "squarely within the realm of traditional state regulation." App., *infra*, 19a-20a.[10]

The court of appeals' application of a presumption against preemption is contrary to decisions of the Eleventh and Fifth Circuits and other courts that have held no presumption is appropriate in conflict preemption cases. The court of appeals' decision is also inconsistent with the practice of this Court, which generally has not applied a presumption in conflict preemption cases.

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[10] Several courts have followed this Court's holding in *Buckman* that no presumption against preemption applies when the subject of the lawsuit involves an area that has not traditionally been regulated by the States. *E.g.*, *Forest Park II* v. *Hadley*, 336 F.3d 724, 731 (8th Cir. 2003) ("[U]nlike cases involving a field traditionally regulated by the states, there is no presumption against preemption in this case."); *Nathan Kimmel, Inc.* v. *DowElanco*, 275 F.3d 1199, 1205 (9th Cir. 2002) (no presumption against preemption for fraud on FDA claim). Given the long history of federal standards for food safety, Petitioner disagrees that Respondent's failure to warn claim involves an area traditionally regulated by the states. In applying a presumption against preemption here, the Third Circuit failed to recognize that an assertion of conflict preemption is a separate reason to proceed without any such presumption.

A. The Court Of Appeals' Decision Conflicts With Decisions Of Other Circuits.

In *Irving* v. *Mazda Motor Corp.*, 136 F.3d 764 (11th Cir. 1998), the Eleventh Circuit considered whether a claim that a seatbelt was defectively designed was expressly or impliedly preempted by the a Federal Motor Vehicle Safety Standard. The court held that while there is a "'strong presumption'" against preemption in express preemption cases, "[w]hen considering implied preemption, no presumption exists against preemption." *Id.* at 767 (quoting *Taylor* v. *Gen. Motors Corp.*, 875 F.2d 816, 823 (11th Cir. 1989)), 769. The Eleventh Circuit rejected the argument that an anti-preemption presumption should apply in conflict cases that involve an area of state concern: "'Under the Supremacy Clause of the Federal constitution, the relative importance to the State of its own law is not material when there is a conflict with a valid federal law,' for 'any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield.'" *Id.* at 769 (quoting *Lewis* v. *Brunswick Corp.*, 107 F.3d 1494, 1502 (11th Cir. 1997)).

The Eleventh Circuit recently confirmed that it does not apply a presumption against preemption in conflict cases: "[I]n practice it is difficult to understand what a presumption in conflict preemption cases amounts to, as we are surely not requiring Congress to state expressly that a given state law is preempted using some formula or magic words." *Florida State Conference of the NAACP* v. *Browning*, 522 F.3d 1153, 1168 (11th Cir. 2008),

(citing *Irving*, 136 F.3d at 769). "Either Congress intended to displace certain state laws or it did not. Federal law is not obliged to bend over backwards to accommodate contradictory state laws, as should be clear from the Supremacy Clause's blanket instruction . . . ." *Id.* The court concluded that it "will not apply a presumption to give less preemptive effect than Congress intended," nor "apply an overly broad construction . . . to give more than Congress intended." *Id.*

The Fifth Circuit has similarly held that, in contrast to *express* preemption cases, "we do not begin with an assumption against *conflict* preemption." *Perry* v. *Mercedes Benz of N. Am., Inc.*, 957 F.2d 1257, 1261-1262 (5th Cir. 1992) (emphasis in original). The Fifth Circuit agrees with the Eleventh Circuit that "'[t]he relative importance to the State of its own law is not material when there is a conflict with a valid federal law,' for 'any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield.'" *Id.* (quoting *Felder* v. *Casey*, 487 U.S. 131, 138 (1988)).[11]

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[11] Lower federal and state courts have similarly declined to apply a presumption against preemption in conflict cases. *See, e.g.*, *Masterson* v. *Apotex, Corp.*, 2008 U.S. Dist. LEXIS 60238, *7-*8 (S.D. Fla. Aug. 7, 2008) ("[T]he presumption against preemption is inapplicable in the context of implied conflict preemption."); *Gentry* v. *Volkswagen of Am., Inc.*, 521 S.E.2d 13, 16 (Ga. App. 1999) ("'[W]hen considering implied preemption, no presumption exists against preemption.'" (quoting *Irving*, 136 F.3d at 769)).

The Third Circuit's application of a presumption against preemption here is directly contrary to the decisions of the Fifth and Eleventh Circuits. By suing under the theory that Petitioner should have included a warning about the risks of methylmercury in tuna, Respondent's tort action conflicts with the nuanced federal policy against food warnings in general, and with FDA's specific policy against warnings for mercury in tuna. The Third Circuit presumed that the action is not preempted, while the Fifth and Eleventh Circuits would not have proceeded from such a presumption.

B. A Presumption Against Preemption In Conflict Cases Is Contrary To This Court's Recent Practice.

While this Court has at times applied a presumption against preemption in express preemption[12] and field preemption cases,[13] the Court's conflict preemption cases, almost without exception, do not apply any presumption against preemption. *See, e.g.*, *Sprietsma* v. *Mercury Marine*, 537 U.S. 51 (2002); *Geier*, 529 U.S. 861; *United States* v. *Locke*, 529 U.S. 89 (2000); *Crosby* v. *Nat'l Foreign Trade Council*, 530 U.S. 363 (2000);

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[12] *See, e.g.*, *Bates* v. *Dow Agrosciences, LLC*, 544 U.S. 431, 449 (2005); *Lohr*, 518 U.S. at 485; *Cipollone*, 505 U.S. at 518.

[13] *English*, 496 U.S. at 79; *Hillsborough County* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 716 (1985); *but see Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238, 247 (1984) (no mention of presumption in field preemption analysis).

Freightliner Corp. v. *Myrick*, 514 U.S. 280 (1995); *Gade* v. *Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88 (1992) (plurality op.); *La. Pub. Serv. Comm'n* v. *FCC*, 476 U.S. 355 (1986); *Wis. Dep't of Indus., Labor & Human Relations* v. *Gould, Inc.*, 475 U.S. 282 (1986); *Allis-Chalmers Corp.* v. *Lueck*, 471 U.S. 202 (1985); *Brown* v. *Hotel & Rest. Employees & Bartenders Int'l Union Local 54*, 468 U.S. 491 (1984); *Capital Cities Cable, Inc.* v. *Crisp*, 467 U.S. 691 (1984).[14]

The Court's decisions in conflict cases have most often emphasized ordinary principles of statutory construction without applying any presumption in favor of or against preemption. For example, in *Geier*, the majority did not mention the presumption against preemption. *See* 529 U.S. at 906-907 (Stevens, J., dissenting) ("the Court simply ignores the presumption [against preemption], preferring instead to put the burden on petitioners to show that their tort claim would not frustrate [federal] purposes"). Instead, the Court relied on "longstanding," "ordinary," and "experience-proved

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[14] While the Court mentioned the presumption in two conflict preemption cases, *California* v. *ARC America Corp.*, 490 U.S. 93, 101 (1989), and *Hillsborough County*, it did not rely on the presumption in its conflict preemption analysis in either case. *ARC*, 490 U.S. at 105-106; *Hillsborough County*, 471 U.S. at 722. Similarly, in two cases that involved claims of both conflict and field preemption, the Court invoked the presumption only in the field preemption analysis and not in the conflict preemption analysis. *See Int'l Paper Co.* v. *Ouellette*, 479 U.S. 481, 491 (1987); *Jones* v. *Rath Packing Co.*, 430 U.S. 519, 525 (1977).

principles of conflict pre-emption." *Geier*, 529 U.S. at 874.

Other recent cases are consistent with *Geier*. In *United States* v. *Locke*, the Court described the presumption as "artificial," declining to invoke it in analyzing whether federal law conflicted with state regulations in "an area where there has been a history of significant federal presence." 529 U.S. 89, 108 (2000). And in *Sprietsma*, the Court did not mention the presumption in its holding that there was no conflict between the Coast Guard's decision not to require propeller guards on boat motors and a purported state tort-law duty to install such guards. 537 U.S. at 64-68. The Court has also recognized that the applicability of the presumption in a conflict preemption case remains an open question. *Crosby*, 530 U.S. at 374 n.8 ("We leave for another day a consideration in this context of a presumption against preemption.").

In *Altria Group, Inc.* v. *Good*, the Court stated that its analysis in "express or implied preemption" questions began with an "'assumption'" that States' "historic police powers" are not preempted "'unless that was the clear and manifest purpose of Congress.'" 129 S.Ct. 538, 543 (2008), (quoting *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). But the Court went on to address the presumption only with regard to express preemption, concluding that "[w]hen the *text of a pre-emption clause* is susceptible of more than one plausible reading, courts ordinarily 'accept the reading that disfavors pre-emption.'" *Id.* at 540 (emphasis added) (quoting *Bates*, 544 U.S. at 449). The Court did not mention

the presumption in its discussion of the conflict preemption question in *Altria Group*. *See id.* at 549-51.[15]

As the Eleventh and Fifth Circuits have held, a presumption against preemption makes little sense in conflict preemption cases. The presumption originated in a field preemption case, with the Court stating that "the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice*, 331 U.S. at 230 (citations omitted). Following *Rice*, in its express preemption cases the Court has applied the presumption as a principle of statutory construction favoring a narrow reading. *Lohr*, 510 U.S. at 485 (the presumption supports "a narrow interpretation of such an express command") (plurality op.); *Cipollone*, 505 U.S. at 518 ("This presumption reinforces the appropriateness of a narrow reading."). But when the issue is whether a state law conflicts with federal law, either because it is impossible to comply with both, or because the state law stands as an obstacle to the accomplishment of the federal law, there is no occasion to make any presumption about congressional intent: Congress intends that its laws will be fully effective, and the Supremacy Clause

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[15] Unlike *Altria Group*, where the government argued that there was no policy that preempted the state cause of action, here FDA's letter concludes that it would be impossible to comply with both FDA's regulatory requirements and state law requiring a warning on the product label concerning methylmercury in fish. *See supra*, pp 23-27.

ensures that "any Thing" to the contrary in State law must yield. As the Court noted in *Geier*:

> Why, in any event, would Congress not have wanted ordinary pre-emption principles to apply where an actual conflict with a federal objective is at stake? Some such principle is needed. In its absence, state law could impose legal duties that would conflict directly with federal regulatory mandates.

529 U.S. at 871. The courts should thus focus on the existence of a conflict between the state and federal law without any presumption that the federal law should be read narrowly not to interfere with the state law.

In the light of this Court's decisions and the disagreement in the courts of appeals over whether the presumption against preemption applies to conflict preemption questions, certiorari should be granted to clarify that no presumption is appropriate in conflict preemption cases.

CONCLUSION

The petition for a writ of certiorari should be granted.[16]

Respectfully submitted,

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January 2009

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[16] This Court heard oral argument in *Wyeth* v. *Levine*, Docket No. 06-1249, on November 3, 2008. *Wyeth* presents the question whether prescription drug labeling judgments made by FDA pursuant to the FDCA preempt state-law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use. *See* Pet. Br. in No. 06-1249, at i. Because of the similarities between this case and *Wyeth*, the Court may wish to hold the petition in this case pending its decision in *Wyeth*, and then dispose of the petition as appropriate in the light of the Court's decision in that case.

APPENDIX

APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NO. 07-1238

DEBORAH FELLNER, individually and on behalf of those similarly situated

v.

TRI-UNION SEAFOODS, L.L.C.
d/b/a CHICKEN OF THE SEA,

Deborah Fellner,
Appellant

On Appeal From the United States District Court
For the District of New Jersey
(D.C. Civil Action No. 06-cv-00688)
District Judge: Hon. Dennis M. Cavanaugh

Argued February 12, 2008

BEFORE: SLOVITER, SMITH and STAPLETON,
Circuit Judges

(Opinion filed: August 19, 2008)

OPINION OF THE COURT

STAPLETON , Circuit Judge:

Plaintiff Deborah Fellner filed this lawsuit against defendant Tri-Union Seafoods, LLC ("Tri-Union") in the Superior Court of New Jersey seeking damages for harm she allegedly sustained as a result of her consumption of methylmercury and other harmful compounds contained in Tri-Union's tuna fish products. The case was removed to federal court, and Tri-Union filed a motion to dismiss for failure to state a claim asserting that Fellner's lawsuit is preempted by regulatory actions of the United States Food and Drug Administration ("FDA"). The District Court granted the motion, ruling that Fellner's claims are preempted by the FDA's "regulatory approach" to the risks posed by mercury compounds in tuna fish. Because we conclude that the FDA has taken no regulatory action which preempts Fellner's lawsuit, we will reverse and remand for further proceedings.

I. Facts and Procedural Background

Fellner alleges that Tri-Union produces, cans and distributes Chicken-of-the-Sea brand tuna fish and that, from 1999 to 2004, her diet consisted almost exclusively of TriUnion's tuna products. She further avers that those products contained methylmercury and other harmful compounds that can result in mercury poisoning and that "[d]ue to the negligence and statutory violations of the Defendant . . . Fellner contracted severe mercury poisoning and suffered extreme physical and emotional injuries." App. at 30a, P 28. She seeks recovery under the New Jersey Products Liability

Act, N.J.S.A. 2A:58C-1, et seq. ("NJPLA"), based on Tri-Union's failure to warn of the risks incurred in consuming its products.[1]

The factual landscape of this case is colored by recent litigation in California. On June 21, 2004, then-Attorney General of California, Bill Lockyer, filed a lawsuit against Tri-Union and other defendants under California's "Proposition 65," CAL. HEALTH & SAFETY CODE § 25249.6, seeking an injunction and civil penalties for defendants' failure to warn consumers that their tuna products contain dangerous mercury compounds. While that suit was pending, the Commissioner of the FDA sent a letter to Mr. Lockyer expressing the opinion that the FDA's prior regulatory actions preempt the State's lawsuit. In the Commissioner's view, the defendants would be unable to comply both with that approach and state law and the existence of the lawsuit would "frustrate the [FDA's] carefully considered federal approach" to the issue of mercury in fish. *See People* v. *Tri-Union Seafoods*, 2006 WL 1544377 (Cal. Super. Ct. May 12, 2006) (taking judicial notice of the letter). In May

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[1] While the complaint refers to a design defect, we find it unclear whether the alleged design defect is the failure to warn or is a claim based on excessive mercury concentrations which is distinct from the failure to warn. The District Court apparently reached the former conclusion; it dismissed the failure-to-warn claim without addressing whether the complaint asserts a separate design-defect claim and whether any such claim is preempted. Due to this posture, and because our disposition of this appeal will result in remand to the District Court, we decline to address the design defect claim, if one there be, and instead will allow the parties to raise these issues before the District Court if they so choose.

2006, following a bench trial, the Superior Court of California found the Attorney General's lawsuit preempted by federal law. *People* v. *Tri-Union Seafoods*, 2006 WL 1544384 (Cal. Super. Ct. May 11, 2006), appeal docketed, No. A116792 (Cal. Ct. App. 1st Dist. Feb. 20, 2007).

Tri-Union removed Fellner's lawsuit to the United States District Court for the District of New Jersey and filed a motion to dismiss for failure to state a claim accompanied by motions requesting that the Court take judicial notice of four documents: (1) a consumer advisory published by the FDA in 2004 regarding the risks of mercury in fish ("the Advisory"); (2) a "backgrounder" for the FDA's 2004 Advisory, which provides further information about those risks ("the backgrounder"); (3) Section 504.0600 of the FDA's Compliance Policy Guide, a guideline recommending that the FDA initiate enforcement action if the concentration of mercury in fish exceeds "1 ppm" ("the Compliance Guide"); and (4) the above-described letter sent by the Commissioner of the FDA to the Attorney General of California ("the Commissioner's letter").

The District Court took judicial notice of the four documents submitted by defendant and granted defendant's motion to dismiss. *Fellner* v. *Tri-Union Seafoods*, 2007 U.S. Dist. LEXIS 1623, 2007 WL 87633 (D.N.J. 2007). It found that the FDA had implemented a "pervasive regulatory scheme" pertaining to the risks of methylmercury in fish consisting of the FDA's Advisory, backgrounder, Compliance Guide, and the Commissioner's letter. It concluded that the FDA had deliberately declined to require warnings in favor of a more "nuanced" and

"balanced" approach consisting of targeted advisories, and that the state law duties relied upon by Fellner in her lawsuit would upset that approach. As a result, the Court dismissed the complaint, holding that the FDA's regulatory scheme regarding mercury in fish preempts Fellner's state law claims. She timely appealed.

II. Jurisdiction and Standard of Review

We have jurisdiction pursuant to 28 U.S.C. § 1291. We exercise plenary review of the District Court's order granting defendant's motion to dismiss. *Santiago* v. *GMAC Mortg. Group, Inc.*, 417 F.3d 384, 386 (3d Cir. 2005). When reviewing a motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6), we accept as true all well-pled factual allegations in the complaint and all reasonable inferences that can be drawn from them, and we affirm the order of dismissal only if the pleading does not plausibly suggest an entitlement to relief. *Wilkerson* v. *New Media Tech. Charter Sch.*, 522 F.3d 315, 321- 22 (3d Cir. 2008).

III. Discussion

The sole question presented in this appeal is whether Fellner's state claim for damages is preempted by federal law. Tri-Union offers three distinct theories of preemption: (1) that the FDA has adopted a "pervasive regulatory approach" -- embodied in the FDA's Advisory, backgrounder and internal enforcement guideline -- with which Fellner's state lawsuit actually conflicts; (2) that the FDA has "reject[ed] the use of warning labels" in favor of a more "nuanced" approach -- that is, that the FDA has reached a decision that warnings

should not be regulated, a decision which preempts the state from entertaining a claim based on a duty to warn theory; and (3) that the FDA would have rejected any warning as "misbranding," a determination which preempts Fellner's failure-to-warn claim.

A. The Doctrine of Federal Preemption

The doctrine of federal preemption is rooted in the Supremacy Clause of the United States Constitution, U.S. Const. art. VI, cl. 2, which invalidates state laws that "interfere with, or are contrary to, federal law." *Hillsborough County* v. *Automated Med. Labs.*, 471 U.S. 707, 712, 105 S. Ct. 2371, 85 L. Ed. 2d 714 (1985) (quoting *Gibbons* v. *Ogden*, 22 U.S. 1 (9 Wheat. 1, 211, 6 L. Ed. 23), (1824)). As we recently explained,

> [t]he Supreme Court has identified three major situations where there is preemption . . . (1) "express" preemption, applicable when Congress expressly states its intent to preempt state law; (2) "field" preemption, applicable when "Congress' intent to pre-empt all state law in a particular area may be inferred [because] the scheme of federal regulation is sufficiently comprehensive" or "the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject;" and (3) "conflict" preemption, applicable when "state law is nullified to the extent that it actually conflicts with federal law," even though

> Congress has not displaced all state law in a given area.

Colacicco v. *Apotex Inc.*, 521 F.3d 253, 261 (3d Cir. 2008) (quoting Hillsborough County, 471 U.S. at 713). *See also English* v. *General Elec. Co.*, 496 U.S. 72, 78-79, 110 S. Ct. 2270, 110 L. Ed. 2d 65 (1990) (summarizing the three types of preemption). Tri-Union has not argued, nor could it, that Fellner's lawsuit is expressly preempted by the Food, Drug and Cosmetics Act ("FDCA") or by federal regulation.[2] Similarly, we do not interpret TriUnion's brief as asserting a field preemption claim, and any such claim would be unavailing.[3] If preemption exists in this case it must be conflict preemption.

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[2] The Act includes an express preemption provision, 21 U.S.C. § 343-1, but Tri-Union does not urge that it governs this case. The inclusion of express preemption provisions does not preclude the operation of ordinary implied preemption principles. *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 869, 120 S. Ct. 1913, 146 L. Ed. 2d 914 (2000).

[3] Courts rarely find field preemption, especially in areas traditionally regulated by the states, unless the structure of a regulatory program leaves little doubt that Congress intended federal law to be exclusive in a particular field. *See, e.g.*, Hillsborough County, 471 U.S. at 717 ("merely because the federal provisions [are] sufficiently comprehensive to meet the need identified by Congress [does] not mean that States and localities [are] barred from identifying additional needs or imposing further requirements in the field . . . . We are even more reluctant to infer preemption from the comprehensiveness of regulations than from the comprehensiveness of statutes . . ."). In this case, the "regulatory scheme" identified by TriUnion and the Commissioner's letter fall far short of the sort of comprehensive federal program ordinarily addressed in field preemption cases.

As the Supreme Court frequently reiterates, in all cases "preemption fundamentally is a question of congressional intent." *English*, 496 U.S. at 78-79. *See also Medtronic* v. *Lohr*, 518 U.S. 470, 485, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996) ("'[t]he purpose of Congress is the ultimate touchstone' in every preemption case") (citation omitted). However, "state laws can be preempted by federal regulations as well as by federal statutes." *Hillsborough County*, 471 U.S. at 713. Where Congress has delegated the authority to regulate a particular field to an administrative agency, the agency's regulations issued pursuant to that authority have no less preemptive effect than federal statutes, assuming those regulations are a valid exercise of the agency's delegated authority. *Fidelity Fed. Savings and Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153-54, 102 S. Ct. 3014, 73 L. Ed. 2d 664 (1982).

Although federal administrative law as well as Congressional enactments are the supreme law of the land, we must reiterate, lest the analysis become unmoored, that it is federal law which preempts contrary state law; nothing short of federal law can have that effect. The Supreme Court's longstanding interpretation of the Supremacy Clause, and indeed the Supremacy Clause itself, mandate this principle:

> Article VI of the Constitution provides that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any states to the Contrary notwithstanding." Art. VI, cl.2. Thus, since our decision in *M'culloch* v. *Maryland*, it has been settled that state

> law that conflicts with federal law is "without effect."

Cipollone, 505 U.S. at 516 (emphasis added). *See also Colacicco*, 521 F.3d at 261 ("[e]arly in our constitutional history, the Supreme Court interpreted this language to invalidate state laws that 'interfere with, or are contrary to,' federal law, the genesis of the preemption doctrine") (emphasis added; citation omitted).

As we have noted, there is no doubt that federal regulations as well as statutes can establish federal law having preemptive force. *New York* v. *Fed. Commc'n Comm'n*, 486 U.S. 57, 63, 108 S. Ct. 1637, 100 L. Ed. 2d 48 (1988) ("The phrase 'Laws of the United States' [in the Supremacy Clause] encompasses both federal statutes themselves and federal regulations that are properly adopted in accordance with statutory authorization"). Although there is some authority for the proposition that the only regulatory process which can produce "federal law" for purposes of the Supremacy Clause is formal, notice and comment rulemaking, *Good* v. *Altria Group*, 501 F.3d 29, 51-52 (1st Cir. 2007), cert. granted, 128 S. Ct. 1119, 169 L. Ed. 2d 846 (2008) (collecting cases), we have joined those courts which hold that, in appropriate circumstances, federal agency action taken pursuant to statutorily granted authority short of formal, notice and comment rulemaking may also have preemptive effect over state law. *Colacicco*, 521 F.3d at 271 (citations omitted).

It is clear, for example, that federal agency orders resulting from quasi-judicial agency proceedings may constitute "federal law" under the

Supremacy Clause: "[i]t is well established that when developing law on a subject, an agency usually has a choice between the method of rulemaking and that of adjudication," *General Motors Corp.* v. *Abrams*, 897 F.2d 34, 39 (2d Cir. 1990) (citation omitted); both agencies' quasi-legislative as well as their quasi-judicial powers "have the binding force of 'federal law.'" *Id.* (citation omitted). *See also Chicago and Nw. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 314-15, 321-28, 101 S. Ct. 1124, 67 L. Ed. 2d 258 (1981) (Interstate Commerce Commission order following quasi-judicial proceeding governing abandonment of rail lines preempted state law). Moreover, in addition to orders from formal adjudicatory proceedings, we have recently given preemptive effect to a federal agency order in a similar situation where a comprehensive federal regulatory scheme authorized a process for the agency to apply a federal standard to concrete circumstances, and it had utilized that process in a manner establishing a federal duty or policy. In *Colacicco*, the plaintiffs' alleged claims for failure to warn that a family of drugs used to treat anxiety and depression caused an increased risk of suicidality. The FDCA conferred jurisdiction upon the FDA to regulate drug labeling. Regulations authorized by the FDCA predicated the marketing of drugs on FDA approval of the drugs' labeling both at the time the drugs were initially marketed and on an ongoing basis thereafter. Defendants' labels had received FDA approval both before and after the suicides at issue. The plaintiffs pointed out, however, that the regulations required that the labeling be revised by the manufacturer unilaterally "to include a warning as soon as there is reasonable evidence of an

association of a serious hazard with a drug." 21 C.F.R. § 201.57(c) (2003). Plaintiffs argued that this meant the defendants could have complied with both the federal regulations and the state duty to warn, and thus no conflict existed. We rejected this argument because, although the regulations allowed a manufacturer to amend warnings unilaterally, all such amendments remained contingent on the manufacturer ultimately receiving FDA approval, and the FDA in a number of different agency proceedings had previously considered the scientific evidence relied upon by plaintiffs and had exercised its prerogative under the regulations to reject suicidality warnings based on that evidence. The FDA had "clearly and publicly stated its position [regarding the propriety of the warning in the pertinent circumstances] prior to the prescriptions and deaths at issue. . . ." *Colacicco*, 521 F.3d at 271. Although defendants had not been shown to be participants in those proceedings, we concluded that a conflict existed because, much like agency quasi-judicial proceedings, *see Security and Exchange Commission* v. *Chenery Corp.*, 332 U.S. 194, 201-03, 67 S. Ct. 1575, 91 L. Ed. 1995 (1947), the FDA's actions in those proceedings established a policy against the sought-after warnings applicable not only to the immediate participants but also to others in like circumstances, such as the defendants. Thus, defendants could not have complied with the requirements of both federal and state law.

This does not mean, however, that federal law capable of preempting state law is created every time someone acting on behalf of an agency makes a statement or takes an action within the agency's

jurisdiction. As the Supreme Court has explained, "[i]t is fair to assume generally that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force." *United States* v. *Mead Corp.*, 533 U.S. 218, 230, 121 S. Ct. 2164, 150 L. Ed. 2d 292 (2001) (addressing which types of agency actions should be afforded Chevron deference). We believe that similar considerations are pertinent here. We decline to afford preemptive effect to less formal measures lacking the "fairness and deliberation" which would suggest that Congress intended the agency's action to be a binding and exclusive application of federal law. Courts with good reason are wary of affording preemptive force to actions taken under more informal circumstances. *See, e.g.*, *Good*, 501 F.3d at 51-52; *Wabash Valley Power Ass'n* v. *Rural Electrification Admin.*, 903 F.2d 445, 453-54 (7th Cir. 1990); *General Motors Corp.*, 897 F.2d at 39. Regularity of procedure -- whether it be the rulemaking and adjudicatory procedures of the APA or others which Congress may provide for a particular purpose -- not only ensures that state law will be preempted only by federal "law," as the Supremacy Clause provides, but also imposes a degree of accountability on decisions which will have the profound effect of displacing state laws, and affords some protection to the states that will have their laws displaced and to citizens who may hold rights or expectations under those laws.

Tri-Union points to the Commissioner's letter as both establishing federal law capable of

preemption and as evidencing the agency's interpretation of previously established law, an interpretation to which we should defer. We evaluate below the deference to which we believe that letter is entitled as an interpretation of pre-existing federal law. With respect to Tri-Union's claim that it established federal law, we note that we have found no case in which a letter that was not the product of some form of agency proceeding and did not purport to impose new legal obligations on anyone was held to create federal law capable of preemption. *See Wabash Valley*, 903 F.2d at 453-54 (declining to give preemptive effect to an agency letter where the prescribed procedures were not followed); *Thomas* v. *New York*, 256 U.S. App. D.C. 49, 802 F.2d 1443 (D.C. Cir. 1986) (same).[4]

Finally, the Supreme Court occasionally has confronted a claim that a federal agency's decision not to regulate should be granted preemptive effect because it constitutes a federal determination that the issue shall be unregulated -- here, the decision not to require (or otherwise regulate) mercury warnings. As the Court explained, "a federal

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[4] Contrary to Tri-Union's suggestion, we do not read *Geier* as indicating otherwise. Although *Geier* declined to require a "specific, formal agency statement identifying a conflict in order to conclude that [] a conflict in fact exists," *Geier*, 529 U.S. at 884, it did require that state law actually conflict with a federal law. The Court ruled that a state lawsuit was preempted because it actually conflicted with a Department of Transportation ("DOT") regulation (FMVSS 208), id. at 874, and the Court merely "place[d] some weight upon the DOT's [informal] interpretation of FMVSS 208's objectives . . .," *id.* at 883, to help it determine whether the two in fact conflicted.

decision to forego regulation in a given area may imply an authoritative federal determination that the area is best left *un*regulated, and in that event would have as much preemptive force as a decision to regulate." *Ark. Elec. Co-op* v. *Ark. Pub. Serv.*, 461 U.S. 375, 384, 103 S. Ct. 1905, 76 L. Ed. 2d 1 (1983) (emphasis in original).

However, the Supreme Court has since cautioned that this statement in Arkansas Electric Co-op "was obviously not meant in an unqualified sense; otherwise, deliberate federal inaction could always imply preemption, which cannot be. There is no federal preemption in vacuo, without a constitutional text or a federal statute to assert it." *P.R. Dep't of Consumer Affairs* v. *Isla Petroleum Corp.*, 485 U.S. 495, 503, 108 S. Ct. 1350, 99 L. Ed. 2d 582 (1988). The Court further explained,

> [w]e are presented with the decidedly untypical claim that federal pre-emption exists despite not only the absence of a statutory provision specifically announcing it, but the absence of any extant federal regulatory program with which the state regulation might conflict and which might therefore be thought to imply pre-emption."

Id. at 500. The Court rejected the claim, concluding that "unenacted approvals, beliefs, and desires are not laws. Without a text that can, in light of those statements, plausibly be interpreted as prescribing federal pre-emption it is impossible to find that a free market was mandated by federal law." *Id.* at 501 (emphasis in original).

The Court again confronted, and rejected, a similar claim just a few years ago. Although the Court acknowledged that the agency had the authority to enact a regime free of any regulation concerning the risk at issue, it declined to infer such a regime from a mere decision not to regulate, absent an "'authoritative' message of a federal policy against [regulation]." *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 67, 123 S. Ct. 518, 154 L. Ed. 2d 466 (2002). The Court explained,

> [i]t is quite wrong to view [the Coast Guard's decision not to adopt a regulation] as the functional equivalent of a regulation prohibiting all States and their political subdivisions from adopting such a regulation . . . . Of course, if a state common-law claim directly conflicted with a federal regulation promulgated under the Act, or if it were impossible to comply with any such regulation without incurring liability under state common law, pre-emption would occur. This, however, is not such a case.

Sprietsma, 537 U.S. at 65 (emphasis added).[5]

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[5] *Sprietsma* discussed the agency's informal, contemporaneous explanation for its decision not to regulate and also emphasized that the agency had taken an anti-preemption position in briefings for the Court. *Sprietsma*, 537 U.S. at 67- 68. We do not interpret *Sprietsma* to have implied that, had the agency adopted a pro-preemption stance in an informal statement or briefings for the Court, those views alone would have imbued the agency's decision not to regulate with preemptive force. (...continued)

Isla Petroleum and *Sprietsma* make clear that mere deliberate agency inaction -- an agency decision not to regulate an issue -- will not alone preempt state law. Furthermore, we find no support for the proposition that an agency's informal explanation for its decision not to regulate can alone imbue such a decision with preemptive force; in all cases concerning alleged "federal determination[s] that [an] area is best left unregulated," *Ark. Elec. Co-op*, 461 U.S. at 384, the Supreme Court and Courts of Appeals have inquired whether some extant law or regulation evinced an "authoritative message of federal policy" that an issue is to remain free of state regulation (or any regulation at all); "unenacted approvals, beliefs, and desires" will not suffice.[6]

Geier directs that courts should consider any views expressed by the agency regarding the purposes and objectives of its actions claimed to preempt state law, and therefore it was only natural for *Sprietsma* to note the agency's agreement. Furthermore, *Sprietsma* emphasized a "stark contrast" with *Geier*: unlike the case before it, in *Geier* it was not mere inaction or a "decision not to regulate" combined with informal agency views that preempted state law but rather a federal regulation (FMVSS 208) that promulgated the "affirmative policy judgment" -- the "authoritative message of a federal policy" -- with which the state lawsuit was found to conflict. *Id.* at 68 (internal quotation marks and citation omitted).

[6] We find only two situations in which courts have given preemptive effect to decisions not to regulate. First, the Supreme Court has found deliberate federal inaction to preempt state law (so-called "negative preemption") through what is essentially a field preemption analysis: "[w]here a comprehensive federal scheme intentionally leaves a portion of the regulated field without controls, then the preemptive inference can be drawn -- not from federal inaction alone, but from inaction joined with action." *Isla Petroleum Corp.*, 485 (...continued)

U.S. at 503 (emphasis in original). In such cases, courts have concluded from the comprehensiveness of a statutory scheme and their interpretation of the purposes and objectives of the statute that Congress intended federal jurisdiction to be exclusive or the field to be free of any regulation whatsoever. *See, e.g., Ark. Elec. Co-op*, 461 U.S. at 384 (citing field preemption case for the proposition that a federal decision to forego regulation may imply an "authoritative federal determination that the area is best left unregulated;" finding no such determination); *Transcontinental Gas Pipe Line* v. *State Oil and Gas Bd.*, 474 U.S. 409, 422, 425, 106 S. Ct. 709, 88 L. Ed. 2d 732 (1986) (finding this brand of field preemption); *Bldg. & Constr. Trades Council* v. *Associated Builders & Contractors*, 507 U.S. 218, 224-27, 113 S. Ct. 1190, 122 L. Ed. 2d 565 (1993) (discussing two lines of such field preemption cases under the NLRA). *Cf. Ray* v. *Atlantic Richfield Co.*, 435 U.S. 151, 178, 98 S. Ct. 988, 55 L. Ed. 2d 179 (1978) (agency's decision not to adopt a particular regulation contributed to a finding of conflict preemption where the agency took the subsequent step of adopting an alternate federal standard governing the issue with which, the Court found, the state rule would be inconsistent).

Second, other such cases appear to be simply express preemption cases -- Congress and federal agencies possessing the appropriate authority certainly may announce by law or regulation a federal policy that an issue is to remain unregulated. *See, e.g., Ark. Elec. Co-op*, 461 U.S. at 388-89 (stating that the federal agency could have announced a policy "that the area is best left unregulated" in a "rule [] valid under the [Act]" but had not done so); *Wabash Valley Power Ass'n*, 903 F.2d at 453-54 (discussing *Ark. Elec. Co-op*); *Gracia* v. *Volvo Europa Truck*, 112 F.3d 291, 296-97 (7th Cir. 1997), *cert. denied*, 522 U.S. 1050, 118 S. Ct. 697, 139 L. Ed. 2d 641 (1998) (explaining that, in contrast to cases where an agency simply declined to regulate an issue, "here there is a specific federal standard . . . [which] determined that this type of vehicle should be exempt from the affixing requirement . . ."); *Lynnbrook Farms* v. *Smithkline Beecham Corp.*, 79 F.3d 620, 625 (7th Cir. 1996), *cert. denied*, 519 U.S. 867, 117 S. Ct. 178, 136 L. Ed. 2d 118 (1996) (agency "declaration" of preemption issued in a formal rule); *Evans* v. *Bd. of County Comm'rs*, 994 F.2d 755, (...continued)

B. Presumption Against Preemption and Deference to the Agency

The parties dispute the applicability of two familiar rules of interpretation. Fellner asserts that we should apply a presumption against preemption. Tri-Union asserts that Fellner's reliance on the presumption against preemption is misplaced, and that in fact we should afford deference to the agency's views on preemption.

1. Presumption Against Preemption

The Supreme Court historically has applied a presumption against the preemption of state laws:

> because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action. In all pre-emption cases, and particularly in those in which Congress has "legislated . . . in a field which the States have traditionally occupied," we "start with the assumption that the historic police powers of the States were not superseded by the Federal Act

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758-60 (10th Cir. 1993) (agency issued a "limited preemption policy" via a "Memorandum Opinion and Order" following notice and comment); *Ray*, 435 U.S. 171-72 (stating that the federal agency could promulgate "rules" announcing that it desired no regulation of an issue but had not done so); *Baltimore & O. R. Co.* v. *Oberly*, 837 F.2d 108, 115-16 and n. 3 (3d Cir. 1988) (citing *Ray*, 435 U.S. at 172-73 & n. 23, and other cases for the same proposition).

> unless that was the clear and manifest purpose of Congress."

Medtronic v. *Lohr*, 518 U.S. 470, 485, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996) (citations omitted). *See also Hillsborough County* v. *Automated Med. Labs.*, 471 U.S. 707, 715, 105 S. Ct. 2371, 85 L. Ed. 2d 714 (1985) ("[w]here . . . the field that Congress is said to have pre-empted has been traditionally occupied by the States 'we start with the [presumption];'") (citation omitted); *Bates*, 544 U.S. at 449 (similar).

Recent Supreme Court jurisprudence suggests that the presumption remains applicable when preemption claims concern areas of the law "which the States have traditionally occupied," but that it may not be applicable "where the interests at stake are 'uniquely federal' in nature." *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 348, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001) (declining to apply the presumption because "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied' . . . . To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character") (citations omitted). *See also United States* v. *Locke*, 529 U.S. 89, 108, 120 S. Ct. 1135, 146 L. Ed. 2d 69 (2000) (presumption applies "in field[s] which the states have traditionally occupied," but declining to apply it because "national and international maritime commerce" is not such a field) (citations omitted).

In the present case, it is hard to imagine a field more squarely within the realm of traditional state regulation than a state tort-like action seeking

damages for an alleged failure to warn consumers of dangers arising from the use of a product. *See, e.g.*, *Bates*, 544 U.S. at 449 ("The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption"). Furthermore, state tort law and other similar state remedial actions are often deemed complementary to federal regulatory regimes, and this appears to be such a case. Federal regulatory programs frequently do not include a compensatory apparatus, and the Supreme Court has recognized that state tort law can also play an important information-gathering role not easily replicated by federal agencies.[7] When a litigant

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[7] *See, e.g.*, *Sprietsma*, 537 U.S. at 64 ("It would have been perfectly rational for Congress not to pre-empt common-law claims, which -- unlike most administrative and legislative regulations -- necessarily perform an important remedial role in compensating accident victims."); *Bates*, 544 U.S. at 449, 451 ("[p]rivate remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA . . . . FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings . . . tort suits can serve as a catalyst in this process;" concluding that "[i]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly"); *Medtronic*, 518 U.S. at 487 (plurality opinion) ("because there is no explicit private cause of action [in the federal Act] . . . [a finding of preemption would mean] Congress would have barred most, if not all, relief for persons injured by defective medical devices. Medtronic's construction of § 360k would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation"); *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238, 251, 104 S. Ct. 615, 78 L. Ed. 2d 443 (1984) ("It is difficult (...continued)

asserts that a private right of action, as opposed to a state statute or regulation, is preempted, we are cognizant that preemption may leave individuals with rights but no private remedy, where traditionally there has been one. Although Congress certainly can afford, and in some instances has afforded, federal regulators exclusive jurisdiction over a particular subject matter, and federal regulations will preempt state laws that actually do conflict with them, we do not lightly infer such a result where state compensatory regimes have traditionally played an important role.

Although we are aware that the Supreme Court has applied the presumption in few conflict preemption cases of late, and arguments have been raised that the conflict preemption analysis subsumes or supplants the presumption, *see Colacicco*, 521 F.3d at 265, we will continue to apply the traditional presumption until the Supreme Court provides guidance to the contrary. *Id. See also Hillsborough County*, 471 U.S. at 715 (applying the presumption to implied preemption claims). However, even where the presumption applies it will be overcome where a Congressional purpose to preempt or the existence of a conflict is "clear and manifest." *Id.*

2. Deference to Federal Agency Views

Tri-Union argues that "the FDA's findings and opinion set forth in the FDA Preemption Letter as

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to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.").

well as its regulatory approach (the FDA Advisory and Backgrounder) should be afforded a high level of deference and/or persuasion." Appellee's Br. at 24.

As we recently explained, "[w]e would ordinarily be leery of an agency's view of what is essentially a legal issue," *Colacicco*, 521 F.3d at 274, but in *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 120 S. Ct. 1913, 146 L. Ed. 2d 914 (2000), the Supreme Court "place[d] some weight," on the agency's informal views of the purposes and objectives of the regulation at issue and the agency's view that the state lawsuit would "stand as an obstacle" to those objectives. *Id.* at 883. We concluded that "such a position is subject to a level of deference approximating that set forth in *Skidmore* v. *Swift & Co.*, 323 U.S. 134, 65 S. Ct. 161, 89 L. Ed. 124 [] (1944)." *Colacicco*, 521 F.3d at 275. As with Skidmore deference, the agency's informal views are entitled to "a respect proportional to [their] 'power to persuade' . . . . [Such informal interpretations] claim the merit of its writer's thoroughness, logic and expertness, [their] fit with prior interpretations, and any other sources of weight." *Mead Corp.*, 533 U.S. at 235 (citation omitted). However, *Geier* does not suggest that courts abdicate their duty to examine whether federal and state law actually conflict -- Geier did not rely exclusively on the agency's views, explaining that it found the conflict "clear enough" even absent those views. *Geier*, 529 U.S. at 886.

The District Court concluded that "the FDA's Advisory and Backgrounder are entitled to deference and [] the FDA Letter is persuasive." *Fellner* v. *Tri-Union Seafoods*, 2007 U.S. Dist. LEXIS 1623, 2007 WL 87633, *7 (D.N.J. 2007). Geier and cases

applying it have afforded some weight to an agency's informal interpretation of the purposes and objectives of its regulations which are claimed to preempt state law. However, the FDA's Advisory and backgrounder are not agency interpretations of regulations claimed to preempt state law but rather are the very agency actions which are claimed to preempt state law. We fail to understand how a court could defer to those documents; they offer no interpretation to which we can defer.

The FDA (indirectly) has offered its interpretation of the purposes and objectives of the regulatory measures at issue in this case in the Commissioner's letter. We agree with the District Court that *Geier* directs us to consider the views expressed in that letter and, as we have explained, those views are entitled to consideration proportional to their ability to persuade: "The weight [accorded to an administrative] judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all of those factors which give it power to persuade, if lacking power to control." *Mead Corp.*, 533 U.S. at 228 (quoting *Skidmore*, 323 U.S. at 140) (bracketed text in original). Here, however, we do not find the letter persuasive. The circumstances of this letter suggest that it merits a particularly low level of deference. The views the FDA there offers, and the significance it there attributes to its prior administrative actions, have not been shown to be

the product of any agency proceeding,[8] were not expressed at the time those actions were taken nor even at the time that Fellner's damages allegedly arose, and are certainly not self-evident from the nature of the actions themselves. The FDA expressed those views only later, through a most informal of methods -- a letter offering a legal theory for the litigation in California. Most importantly, we simply do not find the letter's reasoning persuasive, for the reasons we set forth below.

C. Tri-Union's Three Theories of Conflict Preemption

As we have explained, this is a conflict preemption case. Therefore, Fellner's state law claims will be impliedly preempted if they are "in actual conflict with federal law." *Sprietsma*, 537 U.S. at 64. The Supreme Court has identified two varieties of "conflict" preemption: (1) where "it is

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[8] The District Court granted the motion to dismiss relying solely on the four documents of which it took judicial notice. Accordingly, our record does not provide a full context for the Commissioner's letter. We can only say that the letter does not itself purport to be the product of an agency proceeding, and the record here does not show it to be. The record in the California litigation does reveal that the Commissioner's letter follows, and bears a striking resemblance to, a letter and memorandum that counsel at a private law firm -- counsel who, according to his public law firm biography, represents the canned tuna industry in the California litigation -- sent to the agency's chief counsel urging the FDA to "issue[] an appropriately worded letter" asserting preemption over the litigation in California and offering suggestions for the content of such a letter. The agency had never before expressed such views. Those views apparently were formulated without the benefit of exposure to conflicting views or critiques.

impossible for a private party to comply with both state and federal requirements," and (2) where "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *English*, 496 U.S. at 79 (internal quotation marks and citations omitted).

We begin our analysis by taking note of the authority that Congress has bestowed on the FDA and the extent to which it has exercised that authority in a relevant manner. The FDCA grants the FDA authority to regulate the field of food safety. 21 U.S.C. § 371. The FDA has the authority, inter alia, to promulgate food definitions and standards of food quality, *id.* at § 341, and to set tolerance levels for poisonous substances in food. *Id.* at § 346. The FDA is also delegated enforcement authority, including the authority to take various steps to enforce the Act's ban on "adulterated" or "misbranded" food. *Id.* at §§ 331-336, 342-343. The FDA has, however, promulgated no pertinent regulations under this authority. Nevertheless, it has employed various other means to address the risk of mercury in fish, including issuing a consumer advisory and related "backgrounder" regarding those risks, and including in its internal Compliance Guide a provision recommending that the agency initiate enforcement action if mercury concentrations in fish exceed a specified level. TriUnion offers three theories of conflict preemption based on these actions.

1. Theory 1: Conflict with a Federal Regulatory Scheme

Tri-Union first argues that the FDA has adopted a "pervasive regulatory approach" with

which Fellner's lawsuit actually conflicts. Appellee's Br. at 13, 18-20. This argument suffers from two infirmities. First, as we have explained, state law is preempted only by federal law. The FDA has promulgated no pertinent legal standard pertaining either to the risks posed by mercury in fish or to warnings for that risk, and it has not otherwise acted on the issue in a manner that could be deemed an exclusive application of federal law. Second, even accepting arguendo the FDA's "regulatory scheme" were of a type that could preempt state law, Tri-Union has identified no actual conflict between Fellner's claims and the pertinent FDA actions.

We cannot agree with the District Court that the FDA's Advisory and backgrounder "specifically regulate[]" the levels of methylmercury in tuna and "specifically rejected the notion that warning labels should be included on cans of tuna." *Fellner*, 2007 U.S. Dist. LEXIS 1623, 2007 WL 87633 at *4. That Advisory, titled "What You Need to Know About Mercury in Fish and Shellfish," and the related backgrounder, offer "[a]dvice" for "women who might become pregnant[,] women who are pregnant[,] nursing mothers[, and] young children," App. at 35a, and provide "3 recommendations for selecting and eating fish" that such people are advised to follow. *Id.* We are unable to conclude that the Advisory and backgrounder "specifically regulate[]" anything -- they simply give non-binding advice to a class of consumers and do not promulgate a federal legal standard with which Fellner's state law claims could potentially conflict.

Fellner's lawsuit does not conflict with the "advice" in those documents -- the concerns

expressed therein are entirely consistent with, and arguably complementary to, a duty state law may impose on manufacturers to warn consumers of the risks posed by tuna consumption. *See Bates*, 544 U.S. at 449-51. The mere fact that the FDA chose to warn only certain "at risk" consumers, rather than all consumers, does not create a conflict. Nothing in these documents indicates that consumers other than those "at risk" individuals are not at risk of harm from mercury in fish or that they should not be warned. The Advisory does recommend continued fish consumption within certain parameters, but that recommendation is clearly not inconsistent with a warning against excess consumption.

Tri-Union also points to the FDA's internal enforcement guideline suggesting mercury levels which might prompt FDA enforcement action, and the District Court similarly referenced an FDA "tolerance level" of "1 ppm." *Fellner*, 2007 U.S. Dist. LEXIS 1623, 2007 WL 87633 at *2. *See* FDA Compliance Policy Guide, Section 540.600.[9] Based on this guideline, Tri-Union argues that "[t]he FDA has determined that there is no hazard associated with methylmercury concentrations of less than 1 ppm." Appellee's Br. at 37. We find no such determination. Although the FDA has authority to promulgate standards for food quality and tolerance

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[9] Under the heading "Regulatory Action Guidance," this section offers "criteria for recommending legal action to CFSAN/Office of Compliance/Division of Enforcement: The composite analyzed in accordance with the applicable methods . . . shows: Mercury expressed as Methyl Mercury in excess of 1 ppm (edible portion only)." *Id.*

levels for poisonous foods, 21 U.S.C. §§ 341, 346, it has not done so. The internal guideline for allocation of agency resources "recommend[ed]" in the Compliance Policy Guide will not alone preempt state law.

Furthermore, even if this guideline were deemed a federal standard, Tri-Union fails to explain how Fellner's lawsuit would conflict with it. The guideline states that the FDA may recommend enforcement action if methylmercury concentrations in fish exceed "1 ppm." Much like the Advisory, the guideline appears entirely consistent with, and arguably complementary to, a state claim that Tri-Union wrongfully failed to warn consumers of the risks posed by those compounds. We are aware of no facts establishing the precise mercury concentrations in Tri-Union's tuna products. Even if Fellner had alleged a specific concentration lower than the FDA guideline -- for example, if Fellner had specifically averred that Tri-Union's tuna was dangerous because it contained mercury at a concentration of 0.7 ppm -- such a claim would not necessarily be in conflict with this federal "standard." On its face the guideline does not state that tuna with mercury levels below 1 ppm poses no risk nor that a manufacturer has met any particular standard of care if its tuna does not exceed 1 ppm; it merely suggests that the FDA recommend enforcement action if mercury levels exceed 1 ppm.[10]

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[10] Tri-Union's brief before us emphasizes that the FDA has also conducted an educational campaign regarding mercury in fish and that the FDA discussed mercury in its response to a citizen's petition. We have not been asked to take judicial notice (...continued)

In support of its "pervasive regulatory approach" argument, Tri-Union also points to the Commissioner's letter, in which the Commissioner explains that the FDA prefers to address the risks of mercury in fish through advisories rather than warnings requirements due to the risk of overexposure to warnings and the agency's desire to promote moderate fish consumption. We presume that this is a fair concern. However, the FDA has not acted to regulate it in a manner that could preempt Fellner's claims. As we have explained, the letter itself does not establish a federal policy against warnings capable of preempting state law. As we have also explained, we do not find persuasive the letter's characterization of the FDA's prior actions on the subject as a "regulatory scheme" capable of preempting Fellner's claims.

We conclude that the FDA has regulated neither the risk of mercury in tuna nor the permissible warnings regarding that risk in a manner that conflicts with Fellner's lawsuit.

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of these facts, and it is not clear to us that we could do so in the context of a motion to dismiss and a complaint that does not refer to them directly or indirectly. In any event, we fail to see how an educational campaign might preempt Fellner's lawsuit, and we do not read the response to the citizen's petition to speak to a relevant issue. The citizen's petition concerned not the risks of mercury in fish specifically but rather the impact of dietary supplements of "omega-3 fatty acids" on heart disease. It discusses mercury risks only briefly, in the context of mercury's impact on the health effects of omega-3 fatty acids. The FDA merely explained that it would decline to require that the omega-3 fatty acid health claim be accompanied by a mercury warning, not that all mercury warnings should be affirmatively prohibited.

2. Theory 2: A Federal Decision Not To Regulate

Tri-Union's second theory of preemption is that the FDA has "reject[ed] the use of warning labels," Appellee's Br. at 32 -- that the FDA reached a "federal decision to forego regulation" amounting to "an authoritative federal determination that the area is best left unregulated," a decision which preempts any state standard or duty requiring such warnings. *Id.* at 31 (quoting *Ark. Elec. Co-op.*, 461 U.S. at 384) (emphasis in original). In Tri-Union's view, just such a decision was made when the Commissioner's letter was dispatched. In that letter, the Commissioner expressed the view that, because the FDA after "studying the issue of methylmercury in fish for several years," App. at 42a, declined to require a warning and instead issued an advisory, the California lawsuit would "frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish." *Id.* Although the federal government certainly may promulgate a regulatory regime in which it decides that a particular issue is best left unregulated, as the Supreme Court has explained, "to say that [such a regime] can be created is not to say it can be created subtly." *Isla Petroleum*, 485 U.S. at 500. A mere decision by the FDA not to adopt a federal warnings requirement certainly does not alone preclude states from imposing a duty to warn, and, as we have earlier indicated, we find no authority for the proposition that the FDA could institute a regime affirmatively proscribing all warnings obligations via mere informal expressions of policy such as those in the Commissioner's letter.

Id. at 501, 503 ("[t]here is no federal preemption in vacuo, without a constitutional text or a federal statute to assert it;" "unenacted approvals, beliefs, and desires are not laws").

While the FDA may well have the authority to promulgate a regulatory scheme which would preclude any state duty to warn consumers of the risks of mercury in tuna, it simply has not done so. Tri-Union points to the Commissioner's letter, but as we have explained courts have declined to permit agencies to promulgate express preemption decisions by informal letter. In any event, we do not read the letter as purporting to declare a new preemption policy; it purports to be an explanation of what the FDA determined to do in the past. As we have indicated, however, nothing in the agency's past actions indicates that it made an "authoritative federal determination that the area is best left unregulated."

We have no reason to doubt that the FDA has studied the risks of mercury in fish, as the District Court found. However, it made no "conclusive determination" of the sort which will preempt state law -- neither that mercury in fish poses no adverse health consequences, nor to prohibit some or all warnings. State law is not preempted whenever an agency has merely "studied" or "considered" an issue; state law is preempted when federal law conflicts with state law. As we have explained, the cases leave no doubt that a mere decision not to regulate -- in this case, a decision not to require a federal methylmercury warning -- alone will not preempt state law. *See supra* note 6 and accompanying text. As we have also explained, we find no federal

standard, mandate or regulatory action on the subject with which Fellner's claim conflicts nor any federal determination precluding state regulation of the issue.

3. Theory 3: The FDCA's Food Misbranding Provision

Finally, Tri-Union contends that Fellner's failure-to-warn claim is preempted because that claim is premised on the theory that it should have provided a warning regarding mercury in fish, but the FDA would have deemed any such warning "misbranding," creating a conflict between the asserted state duty and federal law. Appellee's Br. at 33-37. Tri-Union argues that the FDA would deem a warning false and misleading because any such warning would not "specify the scientific basis as to the cause of the harm warned of, and/or the amounts of such food that were required to cause this harm," Appellee's Br. at 34-35, and because a warning would not "balance out the negative methylmercury information with positive information about the numerous healthy attributes of canned tuna," *id.* at 35, resulting in overexposure to warnings and scaring consumers away from a useful product. *Id.* In support of this claim, TriUnion points to the Commissioner's letter, in which the Commissioner opined that the "Proposition 65 warnings" -- the warnings requirement underpinning the California Attorney General's lawsuit -- would be false or misleading for similar reasons.

The FDCA's general misbranding provision for food provides, in pertinent part, that "[a] food shall be deemed misbranded -- (a) False or misleading

label[:] If (1) its labeling is false or misleading in any particular . . . ." 21 U.S.C. § 343(a). FDA regulations further provide that "labeling of a food, drug, device, or cosmetic shall be deemed to be misleading if it fails to reveal facts that are: (1) Material in light of other representations made or suggested by statement, word, design, device, or any combination thereof . . . ." 21 C.F.R. § 1.21. The FDCA renders unlawful, inter alia, the misbranding of food and the distribution of misbranded food, *id.* at § 331(a)-(b), and it authorizes the FDA to enforce those prohibitions via enforcement actions in the United States District Courts for injunctions or criminal penalties. *Id.* at §§ 332, 333. The FDCA also delegates to the FDA certain additional tools to prevent misbranding. The FDA may, and indeed must, officially express its concerns with a warning or label before reporting a violation to a United States Attorney for criminal proceedings, to afford the regulated entity notice and an opportunity to present its views. *Id.* at § 335. In the case of "minor violations," the agency may issue "a suitable written notice or warning." *Id.* at § 336. The FDA is also delegated the authority affirmatively to regulate food labels and warnings.[11]

Had the FDA considered the factual basis for the alleged duty to warn and exercised its misbranding authority to establish that a warning

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[11] *See id.* at §§ 341, 346, 371. The FDA has, for certain other foods, exercised this authority by affirmatively requiring particular warnings, *see, e.g.*, 21 C.F.R. § 101.17, but it has not exercised its regulatory authority in any manner pertinent to this case.

based on that data would be false or misleading under federal law -- not merely that the FDA had failed to require the warning, but had exercised its authority specifically to reject it -- our recent decision in *Colacicco* would govern and a state failure-to-warn lawsuit would be preempted. However, Tri-Union's misbranding theory suffers from the same shortcomings as its prior theories: it identifies no regulatory action establishing mercury warnings as misbranding under federal law, and it fails to explain how the regulatory concerns it has identified actually conflict with Fellner's lawsuit.

The FDA has taken no misbranding action pertaining to the risk of mercury in tuna whatsoever. In the above-listed provisions, Congress provided a broad spectrum of ways in which the FDA may act in order to enforce the statutory prohibition on misbranded food -- "a suitable written notice or warning;" an administrative proceeding of the type required to precede a criminal prosecution; a federal court action seeking an injunction or criminal penalties, and affirmative regulation.[12] However, the FDA has taken no action pursuant to this authority. Instead, the FDA merely expressed an informal policy opinion in a letter, and it did so only after Fellner's injuries were allegedly suffered. We need not decide at what point a particular warning becomes established as false and misleading for preemption purposes. Suffice it to say that the FDA must actually exercise its authority in a manner in

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[12] Ultimately, misbranding liability may be imposed only by federal courts.

fact establishing the state warning as false or misleading under federal law; the informal views expressed in the Commissioner's letter will not preempt Fellner's lawsuit.

Furthermore, as with its other preemption theories, TriUnion fails to identify an actual conflict between the FDA's concerns and Fellner's claims. We perceive no actual conflict between those concerns and Fellner's lawsuit. Had Tri-Union wished to warn consumers of those risks, as Fellner alleges it should have, it is not apparent that Tri-Union would have been unable to do so in a manner that satisfied both the alleged state law duty and the FDA's concerns. For example, a warning certainly could have specified that the risks become material only with frequent tuna consumption, and that moderate fish consumption offers positive health benefits. For these reasons, we find no actual conflict between the FDA's misbranding authority and Fellner's lawsuit.

IV. Conclusion

This is a situation in which the FDA has promulgated no regulation concerning the risk posed by mercury in fish or warnings for that risk, has adopted no rule precluding states from imposing a duty to warn, and has taken no action establishing mercury warnings as misbranding under federal law or as contrary to federal law in any other respect. Fellner's lawsuit does not conflict with the FDA's "regulatory scheme" for the risks posed by mercury in fish or the warnings appropriate for that risk because the FDA simply has not regulated the matter. Fellner's duty-to-warn claim does not conflict with an FDA determination deliberately to

forego warnings because the FDA took no action to preclude state warnings -- at least, no binding action via ordinary regulatory procedures, and no action whatsoever until after Tri-Union allegedly wrongfully failed to warn. Finally, Fellner's lawsuit does not conflict with the FDCA's food misbranding provision or the FDA's actions thereunder because the FDA has not exercised its misbranding authority under the FDCA with respect to methylmercury warnings for fish.

The FDA has only issued a consumer advisory regarding the risks posed by mercury in fish and established a guideline regarding mercury concentrations to guide its enforcement decisions. Neither of these agency acts constitutes a federal legal standard or binding regulatory action on the subject which could give rise to a conflict, and indeed neither expresses a policy or viewpoint or approach inherently inconsistent with Fellner's lawsuit. In the final analysis, this case involves an agency effort to preempt an area of law traditionally within the states' police powers via informal letter, and to do so only after the conduct at issue in this case occurred. We understand the precedent to require more of federal agencies to institute a policy expressly precluding state regulation than a mere informal letter, and neither the Commissioner's letter nor Tri-Union's brief identifies any federal law with which Fellner's lawsuit might conflict. Although the Supremacy Clause provides that state laws will give way when they actually conflict with federal law, on this record we find no federal law with which the alleged state duty to warn conflicts.

For the foregoing reasons, we will reverse the judgment of the District Court and remand the case for further proceedings consistent with this opinion.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DEBORAH FELLNER,
Individually and on Behalf of Those Similarly Situated,

Plaintiffs,

v.

TRI-UNION SEAFOODS, L.L.C.,
d/b/a CHICKEN OF THE SEA,

Defendant.

January 8, 2007, Decided

NOT FOR PUBLICATION

DENNIS M. CAVANAUGH, U.S. District Judge

This matter comes before the Court on motion by Tri-Union Seafoods, L.L.C. ("Defendant") to dismiss the complaint of Deborah Fellner ("Plaintiff") and motion requesting judicial notice in support of its motion to dismiss. For the reasons set forth below, Defendant's motions are granted.

BACKGROUND

Plaintiff's Complaint alleges violations of the New Jersey Products Liability Act, N.J.S.A. 2A-58C-

1, et seq., ("NJPLA"), the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, et seq. ("NJCFA") and common law fraud for failing to warn the public that consumption of Defendant's tuna, purportedly containing methylmercury, could result in mercury poisoning. Plaintiff states that her diet consisted "almost exclusively" of canned tuna for five years between 1999 and 2004. She has been diagnosed with mercury poisoning.

Defendant moves for dismissal, arguing that (1) the United States Food and Drug Administration ("FDA") preempts state law in the areas of establishing the maximum allowable concentration of methylmercury in fish and of warning consumers about the potential effects of methylmercury in tuna when consumed; (2) Defendant is not liable under New Jersey law for injuries incurred by Plaintiff for abnormal consumption of its product; (3) New Jersey law does not impose a duty upon Defendant to warn potential plaintiffs about a product that may be dangerous only if over-consumed; and (4) Plaintiff's claim for common law fraud is subsumed by the NJPLA.

DISCUSSION

Motion Requesting Judicial Notice

In support of its motion to dismiss, Defendant requests that this Court take judicial notice of several publicly available reports and articles on methylmercury in fish. The reports are as follows:

- "What You Need to Know About Mercury in Fish and Shellfish," published by the United States Department of Health and Human Services and

the United States Environmental Protection Agency.

- "Backgrounder for the 2004 FDA/EPA Consumer Advisory: What You Need to Know About Mercury in Fish and Shellfish," published by the United States Department of Health and Human Services ("DHHS") and the United States Environmental Protection Agency. ("EPA").

- Letter from Lester M. Crawford, D.V.M., Ph.D., United States Commissioner of Food and Drugs, to Bill Lockyer, Attorney General of the State of California, dated August 12, 2005, re: a suit filed on June 21, 2004 in San Francisco Superior Court.

- Section 540.600 of the FDA's Compliance Policy Guide allowance of up to one part of methyl mercury per million non-mercury parts of the edible portion of seafood.

Under Federal Rule of Evidence ("FRE") 201, courts can judicially notice public records. *Lum* v. *Bank of America*, 361 F.3d 217, 222 n. 3 (3d Cir. 2004). FRE 201 states:

> A judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.

Fed. R. Evid. 201

This Court has consistently held that it may take judicial notice of public records on motions to dismiss. *Benak* v. *Alliance Capital Mgmt. L.P.*, 349 F.Supp. 2d 882, 889 n. 8 (D.N.J. 2004) (on motion to dismiss court may take judicial notice of publicly available documents and "plaintiffs may therefore be charged with knowledge of relevant public information."). The articles which the Defendant asks this Court to take judicial notice of are all public records and available. This Court, therefore, grants Defendant's motion that this Court take judicial notice of the publicly available information described above.

Methylmercury in Fish

The nature of this action necessitates consideration of the facts regarding mercury in the environment, methylmercury in fish and the FDA's approach to the issue of methylmercury in fish.

Mercury is present in nearly all fish. *See* "What You Need to Know About Mercury in Fish and Shellfish," U.S. Dept. of Health and Human Serv. and the United States Envtl. Prot. Agency EPA-823-R-04-005 (March 2004) (hereinafter "The Advisory"). Mercury is a naturally occurring element in the environment and is also released into the air through industrial pollution. *Id.* Mercury that falls from the air often accumulates in streams, oceans and other bodies of water. *Id.* Fish absorb the mercury as they feed in these waters. *Id.* As a result, mercury becomes part of the fish meat and cannot be removed. *Id.*

The FDA has established tolerance levels for methylmercury in fish through nutritional

guidelines. *See* Fed. Food and Drug Admin. Compliance Policy Guide, § 540.600 (May, 2005). The FDA has also noted that "[r]esearch shows that most people's fish consumption does not cause a health concern." *See* Backgrounder for the 2004 FDA/EPA Consumer Advisory: What You Need to Know About Mercury in Fish and Shellfish at p. 2 (2004) (hereinafter, "Backgrounder"). Additionally, the FDA states that "[f]ish and shellfish can be an important part of [a recommended] diet." *Id.* at 2-3.

Motion to Dismiss

Legal Standard for Granting a Motion to Dismiss

Federal Rule of Civil Procedure 12(b)(6) provides that a court may dismiss a complaint "for failure to state a claim upon which relief can be granted." In deciding a motion to dismiss under Rule 12(b)(6), all allegations in the complaint must be taken as true and viewed in the light most favorable to the plaintiff. *Warth* v. *Seldin*, 422 U.S. 490, 501, 95 S. Ct. 2197, 45 L. Ed. 2d 343 (1975); *Trump Hotels & Casino Resorts, Inc.* v. *Mirage Resorts, Inc.*, 140 F.3d 478, 483 (3d Cir. 1998). However, legal conclusions offered in the guise of factual allegations are given no presumption of truthfulness. *Chugh* v. *Western Inventory Serv., Inc.*, 333 F. Supp. 2d 285, 289 (D.N.J. 2004) (citing *Papasan* v. *Allain*, 478 U.S. 265, 286, 106 S. Ct. 2932, 92 L. Ed. 2d 209 (1986)). While a court will accept well-pled allegations as true for the purposes of the motion, it will not accept bald assertions, unsupported conclusions, unwarranted inferences or sweeping legal conclusions cast in the form of factual allegations. *Morse* v. *Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997).

Claims Under New Jersey Product Liability and Consumer Fraud Acts

Plaintiff's complaint alleges violations of the NJPLA and NJCFA on behalf of herself individually and on behalf of those similarly situated. The allegations are that Defendant knowingly misrepresented, concealed, suppressed, omitted and failed to disclose material information regarding the presence of methylmercury and other harmful compounds in their tuna products with the intent that Plaintiff and members of the class rely upon such concealment. The complaint also accuses Defendant of negligence, breach of the implied warranty of fitness, and strict liability for failure to adequately warn consumers about the mercury compounds contained in its products.

Defendant argues for dismissal of Plaintiff's complaints under the NJCFA and NJPLA because they are preempted by FDA regulations and advisories which specifically address and regulate the issues of allowable amounts of mercury in its product and whether or not the Defendant is required to warn consumers of the dangers of mercury consumption.

The basis for federal preemption is the Supremacy Clause of the Constitution. *Dewey* v. *R.J. Reynolds Tobacco Co.*, 121 N.J. 69, 77, 577 A.2d 1239 (1990). The clause provides that federal law is the "supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. This preemption applies equally to state common law and statutory law. *Feldman* v. *Lederle Lab.*, 125 N.J.

117, 134, 592 A.2d 1176 (1991) *cert. denied*, 505 U.S. 1219, 112 S. Ct. 3027, 120 L. Ed. 2d 898 (1992).

Whether a federal statute preempts state law turns on the intent of Congress when it passed the law and that intention may be either express or implied. *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 516, 112 S. Ct. 2608, 120 L. Ed. 2d 407 (1992). Federal law overrides state law when (1) Congress expressly preempts state law; (2) Congressional intent to preempt can be inferred from the existence of a pervasive federal regulatory scheme; or (3) state law conflicts with federal law or its purposes. *English* v. *General Elec. Co.*, 496 U.S. 72, 78-79, 110 S. Ct. 2270, 110 L. Ed. 2d 65 (1990).

In this case, there is a pervasive federal regulatory scheme implemented by and through the FDA. The FDA has stated that state laws which require warnings regarding methylmercury in fish are preempted under federal law. *See* Letter from Lester M. Crawford, D.V.M., Ph.D., United States Commissioner of Food and Drugs ("Commissioner Crawford"), to Bill Lockyer, Attorney General of the State of California, dated August 12, 2005, re: a suit filed on June 21, 2004, in San Francisco Superior Court ("FDA Letter").

On June 21, 2004, the Office of the Attorney General of California filed suit seeking an injunction and civil penalties against the Tri-Union Seafoods, LLC, for failing to warn consumers that canned and packaged tuna products were exposing consumers to mercury compounds. *The People of the State of California* v. *Tri-Union Seafoods, LLC, et al.*, 2006 WL 1544377 (Cal. Super. Case No.: CGC-04-432394). In response to the suit, Commissioner Crawford

wrote the FDA Letter which explained that the warnings sought by California would "frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish." *See* FDA Letter at p. 1.

The FDA Letter also explained that the "FDA has been studying the issue of methylmercury in fish for several years. In so doing, it has compiled substantial data, and has developed significant expertise in analyzing the pertinent scientific issues, together with the consumer education aspects of this matter. As a result, the agency believes that it is uniquely qualified to determine how to handle the public health concerns related to methylmercury in fish. After many years of analysis on this issue, [the] FDA has chosen to issue an advisory rather than to require a warning on fish and shellfish product labels for several reasons." *See* FDA Letter at p. 2.

The FDA issued its 2004 methylmercury advisory to, "inform women who may become pregnant, pregnant women, nursing mothers, and parents of young children as to how to get the positive health benefits from eating fish and shellfish, while minimizing their mercury exposure." *See* FDA Letter at p. 4. The Advisory specifically regulates the levels of methylmercury allowed in canned tuna and specifically rejected the notion that warning labels should be included on cans of tuna. *Id.*

Plaintiff argues that the FDA does not preempt New Jersey state law for failure to warn of the dangers of mercury in the Defendant's tuna. There is a presumption in the law against preemption. *New York Conference of Blue Shield*

and Blue Cross Plans v. *Travelers Ins. Co.*, 514 U.S. 645, 655, 115 S. Ct. 1671, 131 L. Ed. 2d 695 (1995). The burden is on the proponent of preemption to overcome the presumption against finding that areas traditionally regulated by the states, such as products liability or consumer protection laws, have been preempted. *Hillsborough County* v. *Automated Med Lab.*, 471 U.S. 707, 716, 105 S. Ct. 2371, 85 L. Ed. 2d 714 (1985).

Plaintiff suggests that the Defendant has failed to carry its burden to overcome the presumption against a finding that either the NJPLA or NJCFA have been preempted by the FDA's actions. In support of its position, Plaintiff states that The Advisory and Backgrounder are not entitled to deference and that the FDA Letter is not persuasive.

Plaintiff explains that the FDA has not officially prohibited mercury warnings on cans of tuna regarding methylmercury. For this proposition, Plaintiff argues that the FDA Letter is not entitled to deference from this Court. "Interpretations contained in formats such as an opinion letter are entitled to respect, . . . but only to the extent that those interpretations have the power to persuade." *Christensen* v. *Harris County*, 529 U.S. 576, 587, 120 S. Ct. 1655, 146 L. Ed. 2d 621 (2000).

The New Jersey Supreme Court ruled that the lack of a formal FDA requirement for additional warnings on a product does not create a conclusive presumption that labeling which satisfies the FDA also constitutes an adequate warning under state law. *Feldman* v. *Lederle Lab.*, 125 NJ 117, 592 A.2d 1176 (NJ 1991), *cert. den.*, 505 U.S. 1219, 112 S. Ct.

3027, 120 L. Ed. 2d 898 (1992). As such, if this Court finds that the FDA's regulatory scheme, as described in the Advisory and Backgrounder, is not entitled to deference and that the FDA Letter is not persuasive, then Defendant could comply with both New Jersey and federal law by placing warning labels on their tuna products.

The essential issue is whether the FDA's regulatory scheme as explained and embodied in the FDA Letter, Advisory and other materials is entitled to deference from this Court. In arguing that this Court should not defer to the FDA's interpretation of its regulatory scheme in this area, Plaintiff points to the FDA Letter and calls it too informal. In her brief, Plaintiff states that the FDA Letter "appears to have been solicited for the express purpose of derailing litigation against [Defendant] and other seafood companies." Therefore, Plaintiff reasons, the FDA Letter and arguments contained therein are not the product of independent analysis by the FDA, but are simply the parroting of arguments designed to benefit the Defendant and other industry members in this and other potential lawsuits.

An examination of the FDA's response to the potential health hazards of methylmercury in food reveals that the FDA has been collecting data and addressing this concern for years. The FDA issued its first methylmercury fish advisory in the mid 1990s. *See* FDA Letter at p. 3. Since that time, the FDA has compiled more data and has developed significant expertise in analyzing the scientific issues and consumer education aspects of this matter.

After studying the data, the Foods Advisory Committee ("FAC") recommended that the FDA and

EPA jointly issue an advisory about mercury in fish for women who might become pregnant, women who are pregnant, nursing mothers and young children. *See* Advisory at p. 1.

On March 19, 2004, the FDA and EPA released The Advisory, with the following message:

> Message to Consumers:
>
> Fish and shellfish are important parts of a healthy and balanced diet. They are great sources of high quality protein and other nutrients. However, depending on the amount and type of fish you consume it may be prudent to modify your diet if you are planning to become pregnant; pregnant; nursing; or a young child. With a few simple adjustments, you can continue to enjoy these foods in a manner that is healthy and beneficial and reduce your unborn or young child's exposure to the harmful effects of mercury at the same time.

See Advisory at p. 1.

The Backgrounder to the Advisory, released simultaneously, clearly emphasizes the importance of continuing to eat fish as part of a healthy diet:

> The Difference Between this Advisory and Previous Advisories:
>
> 1. The advisory emphasizes the positive benefits of eating fish.
>
> 2. The advisory provides examples of commonly eaten fish that are low in mercury.

* * *

What's Next:

FDA and EPA want to ensure that women and young children continue to eat fish and shellfish because of the nutritional benefits and encourage them to follow the advisory so they can be confident in reducing their mercury exposure as well.

See Backgrounder at p. 2.

Plaintiff argues that the FDA Letter is merely an *ex parte* communication intended to derail litigation against the seafood industry. However, the FDA Letter aside, both the Advisory and Backgrounder excerpted above were released in March, 2004. The California litigation to which the FDA Letter responds commenced on June 21, 2004. Therefore, the Advisory and Backgrounder which evidence a clear effort by the FDA and EPA to encourage the continued public consumption offish, were released before the complaint in the California case had even been filed. Clearly, the FDA had already taken the position against blanket warning labels before the California suit which prompted the FDA Letter.

In advocating the position that the Advisory and Backgrounder have no preemptive effect on the NJCFA and NJPLA, Plaintiff argues that the mere existence of a federal regulatory or enforcement scheme does not by itself imply preemption. *English.*, 110 S. Ct. at 2279 (1990). Plaintiff's opposition to Defendant's motion to dismiss characterizes the Advisory and Backgrounder as

"minuscule" actions which are not official regulations and, therefore, not sufficient to preempt state law.

However, it is not uncommon for the FDA to specifically choose the issuance of an advisory rather than an official warning In his letter to the California Attorney General, Commissioner Crawford explained, "[f]irst, consumer advisories are communicated to the target audience directly, rather than to all consumers. Second, the FDA believes that the advisory approach is more effective than a product label statement in relaying the complex messages about mercury in seafood. Third, a label statement that reaches the public at large can also have unintended adverse public health consequences. FDA focus group results have suggested that people who are not in the target audience . . . might eat less fish or refrain from eating fish altogether when they receive information about the mercury content of fish . . ." FDA Letter at p. 2-3.

In holding that a formal explicit agency statement is not necessary for the finding of a preemptive intent, the Supreme Court of the United States explained,

> "the Court has never before required a specific formal agency statement identifying conflict in order to conclude that such a conflict in fact exists. Indeed, one can assume that Congress or an agency ordinarily would not intend to permit a significant conflict.

Geier v. *Am. Honda Motor Co.*, 529 U.S. 861, 884-85, 120 S. Ct. 1913, 146 L. Ed. 2d 914 (2000).

In *Geier*, the Supreme Court of the United States examined the Department of Transportation's interpretation of the regulation at issue's objectives and the Department's conclusion that tort suits, like the suit against American Honda Motor Co., would stand as an obstacle to the accomplishment and execution of those objectives. The Court reasoned that "the agency is likely to have a thorough understanding of its own regulation and its objectives and is 'uniquely qualified' to comprehend the likely impact of state requirements." *Id.* at 883 (quoting *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 496, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996)).

Deference to an agency's interpretation of its own powers is appropriate when the regulatory scheme is silent as to preemption. *Barnhart* v. *Thomas*, 540 U.S. 20, 26, 124 S. Ct. 376, 157 L. Ed. 2d 333 (2003). Here, the FDA Letter in response to the California litigation only crystallizes the already transparent intent of the FDA to preempt state law that might interfere with the FDA's concern that warnings on tuna products may upset the desired balance between informing consumers of both the benefits and risks of fish consumption:

> [The] FDA believes that such warnings are preempted under federal law. They frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish; accordingly federal law preempts [California's] warnings concerning mercury and mercury compounds in tuna. Furthermore, [the] FDA believes that

> compliance with both the FDA and [the California warning] is impossible and, as a result, the latter is preempted under federal law.

See FDA Letter p. 1-2

Commissioner Crawford also explained that, "rather than requiring warnings for every single ingredient or product with possible deleterious effects, the FDA has deliberately implemented a more nuanced approach, relying primarily on disclosure of ingredient information and nutrition information...in order to avoid overexposing consumers to warnings, which could result in them ignoring all such statements, and hence creating a far greater public health problem." *Id.*

For the reasons discussed above, this Court finds that the FDA's Advisory and Backgrounder are entitled to deference and that the FDA Letter is persuasive. Therefore, applying the carefully structured and implemented regulatory scheme of the FDA to Plaintiff's allegations that Defendant was required by New Jersey law to provide warnings about methylmercury and that Defendant's failure to warn constituted a violation of the NJCFA, shows that it would be impossible for Defendant to comply with the FDA and New Jersey law.

It is worth noting that the FDA's regulatory approach has been in effect and has preempted New Jersey state law for the entire period that the Plaintiff's diet consisted almost exclusively of canned tuna (1999-2004). The FDA's published its first methylmercury in seafood advisory in the mid-1990s. *See* FDA Letter at p. 3.

The FDA's regulatory scheme is the result of over ten years of data collection and study. Plaintiff suggests that this Court dismiss the FDA's analysis and deliberately nuanced response to the issue of methylmercury found in seafood. To ask that this Court ignore the evidence of the FDA's carefully balanced approach in favor of Plaintiff's claim that the FDA's treatment of this issue is a contrived response to potential lawsuits against the seafood industry distorts logic. This Court will not turn a blind eye to the evidence of the FDA's ten-year deliberately balanced approach to the issue of methylmercury in fish.

This Court, therefore, grants Defendant's motion that Counts I, II and III of Plaintiff's complaint be dismissed.

Claims Under Common Law Fraud

Plaintiff alleges that the actions of Defendant constitute fraudulent conduct, including but not limited to, knowingly making material misrepresentations and omissions regarding Defendant's tuna products upon which Plaintiff reasonably relied. Defendant argues that Plaintiff's common law fraud claims must be dismissed because they are subsumed by the NJPLA.

In *Estate of Brown* v. *Philip Morris, Inc.*, 228 F. Supp. 2d 506 (D.N.J. 2002), the decedent's wife brought suit against three cigarette manufacturers asserting that smoking resulted in the death of her husband and alleging both a violation of the NJPLA and common law fraud. *Id.* The court held that the NJPLA "clearly subsumes plaintiff's common-law claims." *Id.* at 516. Put another way, plaintiffs

cannot recast a product liability claim as a fraud claim. *Walus* v. *Pfizer, Inc.*, 812 F.Supp. 41, 45 (D.N.J. 1993).

Count IV of Plaintiff's complaint alleges common law fraud asserting exposure to "unsafe methylmercury and other harmful compounds that could result in mercury poisoning." Counts I and II allege a violation of the NJPLA. As was the case in Estate of Brown, Plaintiff merely "recasts [her] product liability claims" as fraud claims.

Plaintiff's common law fraud claim is pled in violation of the NJPLA's single cause of action rule. This Court, therefore, grants Defendant's motion that Count IV of Plaintiff's complaint be dismissed.

CONCLUSION

Based on the foregoing, Defendant's Motion to Dismiss Plaintiff's complaint is granted. An appropriate Order accompanies this Opinion.

/S Dennis M. Cavanaugh, U.S.D.J.

Date: Jan. 8, 2007

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NO. 07-1238

DEBORAH FELLNER, individually and
on behalf of those similarly situated

v.

TRI-UNION SEAFOODS, L.L.C.
d/b/a CHICKEN OF THE SEA;

Deborah Fellner,
Appellant

SUR PETITION FOR REHEARING

BEFORE: SCIRICA, Chief Judge, SLOVITER, McKEE, RENDELL, BARRY, AMBRO, FUENTES, SMITH, FISHER, CHAGARES, JORDAN, HARDIMAN and STAPLETON,*
Circuit Judges

The petition for rehearing filed by appellee in the above-entitled case having been submitted to the judges who participated in the decision of this Court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in

---

* Senior Circuit Judge Walter K. Stapleton was a member of the original panel. His vote is limited to panel rehearing.

regular active service not having voted for rehearing by the court en banc, the petition for rehearing is denied.

By the Court,

/s/ Walter K. Stapleton
Circuit Judge

Dated: 15 September 2008

Relevant Provisions Of The Food, Drug, And Cosmetics Act, 21 U.S.C. § 301 *et seq.*

§ 321. Definitions; generally

* * *

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the articles to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

* * *

§ 343. Misbranded food

A food shall be deemed to be misbranded--

(a) False or misleading label. If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 411 [21 U.S.C. § 350] applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 411(b)(2) [21 U.S.C. § 350(b)(2)].

* * *

(f) Prominence of information on label. If any word, statement, or other information required by or under

authority of this Act [21 U.S.C. §§ 301 et seq.] to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

* * *

(v) Failure to label; health threat. If--

(1) it fails to bear a label required by the Secretary under section 801(n)(1) [21 U.S.C. § 381(n)(1)] (relating to food refused admission into the United States);

(2) the Secretary finds that the food presents a threat of serious adverse health consequences or death to humans or animals; and

(3) upon or after notifying the owner or consignee involved that the label is required under section 801 [21 U.S.C. § 381], the Secretary informs the owner or consignee that the food presents such a threat.

* * *

§ 343-1. National uniform nutrition labeling

(a) Except as provided in subsection (b), no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce--

(1) any requirement for a food which is the subject of a standard of identity established under section 401 [21 U.S.C. § 341] that is not identical to such standard of identity or that is not identical to the

requirement of section 403(q) [21 U.S.C. § 343(q)], except that this paragraph does not apply to a standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 401 and 403(g) [21 U.S.C. §§ 341 and 343(g)],

(2) any requirement for the labeling of food of the type required by section 403(c), 403(e), 403(i)(2), 403(w), or 403(x) [21 U.S.C. § 343(c), (e), (i)(2), (w), or (x)] that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 403(c) [21 U.S.C. § 343(c)] and that is applicable to maple syrup,

(3) any requirement for the labeling of food of the type required by section 403(b), 403(d), 403(f), 403(h), 403(i)(1), or 403(k) [21 U.S.C. § 343(b), (d), (f), (h), (i)(1) or (k)] that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 403(h)(1) [21 U.S.C. § 343(h)(1)] and that is applicable to maple syrup,

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) [21 U.S.C. § 343(q)], except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 403(q)(5)(A) [21 U.S.C. § 343(q)(5)(A)(i) or (ii)], or

(5) any requirement respecting any claim of the type described in section 403(r)(1) [21 U.S.C. § 343(r)(1)] made in the label or labeling of food that

is not identical to the requirement of section 403(r) [21 U.S.C. § 343(r)], except a requirement respecting a claim made in the label or labeling of food which is exempt under section 403(r)(5)(B) [21 U.S.C. § 343r(5)(B)].

Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990 [note to this section].

(b) Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a), under such conditions as may be prescribed by regulation, any State or local requirement that--

(1) would not cause any food to be in violation of any applicable requirement under Federal law,

(2) would not unduly burden interstate commerce, and

(3) is designed to address a particular need for information which need is not met by, the requirements of the sections referred to in subsection (a).

§ 346. Tolerance for poisonous or deleterious substances in food; regulations

Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a) [21 U.S.C. § 342(a)(2)(A)]; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of

public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a) [21 U.S.C. § 342(a)(2)(A)]. While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a) [21 U.S.C. § 342(a)(1)]. In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

Relevant Provisions Of The Nutrition Labeling And Education Act of 1990, 104 Stat. 2353

* * *

[Sec. 6] (c) CONSTRUCTION.

(1) The Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A of the Federal Food, Drug, and Cosmetic Act.

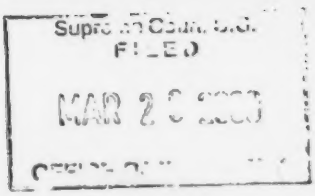
(2) The amendment made by subsection (a) and the provisions of subsection (b) shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning

concerning the safety of the food or component of the food.

(3) The amendment made by subsection (a), the provisions of subsection (b) and paragraphs (1) and (2) of this subsection shall not be construed to affect preemption, express or implied, of any such requirement of a State or political subdivision, which may arise under the Constitution, any provision of the Federal Food, Drug, and Cosmetic Act not amended by subsection (a), any other Federal law, or any Federal regulation, order, or other final agency action reviewable under chapter 7 of title 5, United States Code.

* * *

4



(4)

No. 08-889

IN THE
Supreme Court of the United States

TRI-UNION SEAFOODS, L.L.C,
D/B/A CHICKEN OF THE SEA,

Petitioner,

v.

DEBORAH FELLNER,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

RESPONDENT'S BRIEF IN OPPOSITION

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March 2009

QUESTIONS PRESENTED

1. Whether the Third Circuit correctly held that Deborah Fellner's state-law claims based on failure to warn of the risks of mercury in tuna are not preempted by the Food and Drug Administration's issuance of an advisory to pregnant women, nursing women, women who might become pregnant, and young children about mercury in seafood; by its decision not to require mercury warnings as a condition of placing health claims related to omega-3 fatty acids on seafood; and by its sending of an informal letter to a party in another case stating the view that the particular state law at issue in that case was preempted.

2. Whether the presumption against preemption—reaffirmed by the Court twice already this Term in conflict preemption cases—continues to apply in such cases.

TABLE OF CONTENTS

QUESTIONS PRESENTED. i

TABLE OF AUTHORITIES. iii

INTRODUCTION. 1

STATEMENT OF THE CASE. 1

A. Factual Background. 1

B. Proceedings Below. 5

REASONS FOR DENYING THE WRIT. 9

I. The Decision Below is Consistent with *Dowhal* and This Court's Precedent. 9

II. The Decision Below Would Not Allow Tri-Union to Be Held Liable for Failing to Include a Warning That Would Violate Federal Law. . . . 12

III. This Court Has Reaffirmed the Presumption Against Preemption Twice Already This Term in Conflict Preemption Cases. 14

CONCLUSION. 16

TABLE OF AUTHORITIES

CASES Pages

Altria Group, Inc., v. Good,
129 S. Ct. 538 (2008) 14, 15

Arkansas Electric Cooperative Corp. v. Arksansas Public Service Commission, 461 U.S. 375 (1983). . 12

California v. ARC America Corp.,
490 U.S. 93 (1989) 15

Dowhal v. SmithKline Beecham Consumer Healthcare, 32 Cal. 4th 910 (2004)..... 1, 9

Grocery Manufacturers of America, Inc. v. Gerace,
755 F.2d 993 (2d. Cir. 1985) 13

Hillsborough County v. Automated Medical Laboratories, Inc., 471 U.S. 707 (1985)..... 15

Puerto Rico Department of Consumer Affairs v. Isla Petroleum Corp., 485 U.S. 495 (1988)..... 12

Skidmore v. Swift & Co.,
323 U.S. 134 (1944)..... 10

United States v. Mead Corp.,
533 U.S. 218 (2001)..... 6, 10

Wyeth v. Levine,
__ U.S.__, No. 06-1249 (March 4, 2009)..... *passim*

STATUTES Pages

21 U.S.C. § 343(a)(1). 14

Cal. Health and Safety Code § 25249.6. 3

N.J.S.A. 2A:58-C. 5

N.J.S.A. 56:8-1. 5

INTRODUCTION

The Food and Drug Administration ("FDA") has "promulgated no regulation concerning the risk posed by mercury in fish or warnings for that risk, has adopted no rule precluding states from imposing a duty to warn, and has taken no action establishing mercury warnings as misbranding under federal law or as contrary to federal law in any other respect." Pet. App. 35a. Nonetheless, Petitioner Tri-Union Seafoods urges this Court to review the Third Circuit's decision that Deborah Fellner's state-law claims based on failure to warn of the risks posed by mercury in seafood are not preempted by the FDA's "regulatory actions." Pet. 15. As *Wyeth v. Levine*, __ U.S.__, No. 06-1249 (March 4, 2009), makes clear, however, the court of appeals correctly held that the FDA's few informal actions on mercury in seafood do not constitute federal law capable of preempting state law under this Court's Supremacy Clause jurisprudence. Moreover, the decision below does not conflict with *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910 (2004), just because both cases involve agency letters. As for Tri-Union's second question presented, the Court has reaffirmed the presumption against preemption twice already this Term and has rejected the argument that it does not apply to conflict preemption cases. The petition for a writ of certiorari should be denied.

STATEMENT OF THE CASE

A. Factual Background

1. Methylmercury is a highly toxic form of mercury that builds up in fish and other seafood. Despite the dangers of methylmercury in seafood, the FDA has issued no regulations pertaining to it: It has not placed a regulatory limit on the acceptable amount of mercury in

seafood; it has not promulgated labeling regulations pertaining to mercury in seafood; and it has not issued regulations either requiring or forbidding warnings about mercury in seafood.

What the FDA has done is provide some consumers with advice about mercury through a brochure and its website. In particular, the FDA has made advice available to women who might become pregnant, women who are pregnant, nursing mothers, and young children in an advisory entitled "What You Need to Know About Mercury in Fish and Shellfish" (the "Consumer Advisory"), available at http://www.cfsan.fda.gov/~dms/admehg3.html. The Consumer Advisory states that fish and shellfish are an important part of a healthy diet, but that they contain traces of mercury and "some fish and shellfish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system." *Id.* It counsels the women and children at whom it is aimed to avoid shark, swordfish, king mackerel, and tilefish; to eat no more than 12 ounces a week of other fish (including canned light tuna) and no more than 6 ounces a week of albacore tuna; and to check local advisories about freshly caught fish. *Id.* Neither the Consumer Advisory nor the backgrounder that accompanied it mentions food labels or warnings or sets limits on mercury levels in canned tuna.

The FDA has also issued non-binding guidance to its enforcement division setting forth a level of mercury—called an "action level"—above which the seafood may be considered adulterated. *See* http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg540-600.html (providing "criteria for recommending legal action").

2. In September 2004, the FDA addressed a different issue related to seafood: whether food producers could make claims about the health benefits of eating foods containing omega-3 fatty acids. The FDA issued a letter stating that it would not take enforcement action against manufacturers of foods that claimed that "supportive but not conclusive research" shows that eating certain omega-3 fatty acids may reduce the risk of heart disease. At the same time, the FDA rejected a request by Martek Biosciences Corporation that it require any such claims on seafood to be accompanied by a label statement about the harmful effects of mercury. *See* Letter from William K. Hubbard, FDA, to Martin J. Hahn, Hogan & Hartson, Responding to Health Claim Petition dated November 3, 2003 (Martek Petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease (the "Martek Petition Response"), available at http://www.cfsan.fda.gov/~dms/ds-ltr37.html. In other words, the FDA decided that it would not consider seafood bearing an omega-3 fatty acid health claim to be misbranded just because the claim was not accompanied by a mercury warning. *See id.* ("FDA has decided that it would be preferable not to use a label statement about mercury . . . as a condition for the agency's enforcement discretion for the omega-3 fatty acid qualified health claims."); *compare* Pet. at 8, 19 (quoting only first part of sentence).

3. In June 2004, the State of California sued Tri-Union and other tuna companies under the state's Safe Drinking Water and Toxic Enforcement Act of 1986, Cal. Health and Safety Code § 25249.6 (commonly referred to as "Proposition 65"), for selling canned tuna without a warning that the products contained mercury. During

discovery in that case, the defendants produced an unsigned letter and memorandum dated August 12, 2004, to the FDA Chief Counsel, from an attorney at Covington & Burling, which represented the canned tuna industry in the litigation. *See* Court of Appeals App. A-75 - A-98. The letter urged the FDA to send a letter to California officials stating that the FDA intended to preempt Proposition 65 warnings on tuna. The memorandum explained that "the language of the Supreme Court's decisions . . . suggests that only . . . a binding rule of law promulgated pursuant to the agency's delegated rule-making authority from Congress, qualifies as a 'Law of the United States' for purposes of preemption under the Supremacy Clause." *Id.* A-80. Nonetheless, the memorandum stated that a court might give deference to a letter from the FDA asserting the intent to preempt Proposition 65 mercury warnings. The memorandum detailed points that the FDA should make in such a letter.

Parroting many of the arguments and some of the exact language in the Covington & Burling memorandum, on August 12, 2005, the FDA Commissioner sent the California Attorney General the requested letter expressing the "belie[f]" that the specific warnings at issue in that case were preempted by federal law. *See* Letter from Lester M. Crawford, Commissioner of Food and Drugs, to Bill Lockyer, Attorney General of the State of California, RE: a suit filed on June 21, 2004 in San Francisco Superior Court, *The People of the State of California v. Tri-Union Seafoods, LLC, et al.* (the "Commissioner's Letter"), available at http://www.cfsan.fda.gov/~dms/fl-ltr65.html. The Commissioner's Letter asserted that the FDA "implemented its regulatory

authority with a nuanced approach," and that the "Proposition 65 warnings frustrate this carefully considered agency approach, causing federal law to preempt California's warnings." *Id.* The letter also contended that the FDA believed that the Proposition 65 warnings would be misleading because they "omit facts which are necessary to place the information in its proper context," and that, therefore, tuna products with the Proposition 65 warnings would be misbranded under federal law. *Id.*

B. Proceedings Below

Deborah Fellner developed severe mercury poisoning after making Tri-Union Seafood's tuna a primary part of her diet between 1999 and 2004. On January 16, 2006, she filed this action for damages under the New Jersey Products Liability Act, N.J.S.A. 2A:58-C et seq., and the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq. Tri-Union moved for judicial notice of the Consumer Advisory, backgrounder, Commissioner's Letter, and action level, and to dismiss on the ground that Ms. Fellner's claims are preempted by the FDA's actions. On January 8, 2007, the district court granted both motions. Pet. App. 38a.

The Third Circuit reversed. The court began by explaining that regulations, as well as statutes, can preempt state law and that, under its case law, agency action may be preemptive even if it is not taken through notice-and-comment rulemaking. *Id.* 9a. However, the court stated, that "does not mean . . . that federal law capable of preempting state law is created every time someone acting on behalf of an agency makes a statement

or takes an action within the agency's jurisdiction." *Id.* 11a-12a. Noting that the Supremacy Clause provides that state law will be preempted only by federal "law," the court held that preemptive effect should not be afforded to informal measures "lacking the 'fairness and deliberation' which would suggest that Congress intended the agency's action to be a binding and exclusive application of federal law." *Id.* 12a (quoting *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001)). With regard to the Commissioner's Letter, the court stated that it had found no case in which a letter that was not the product of an agency proceeding and did not purport to impose new legal obligations on anyone was held to be federal law capable of preemption. *Id.* 13a. It also pointed out that "mere deliberate agency inaction" does not alone preempt, and that it could find "no support for the proposition that an agency's informal explanation for its decision not to regulate can alone imbue such a decision with preemptive force." *Id.* 16a.

The court next discussed two rules of interpretation: the presumption against preemption and deference. The Court stated that the presumption applied here because "it is hard to imagine a field more squarely within the realm of traditional state regulation than a state tort-like action seeking damages for an alleged failure to warn consumers of dangers arising from the use of a product." *Id.* 19a-20a. With regard to deference, the court explained that an agency's informal views on a legal issue are entitled to deference in accordance with their power to persuade. *Id.* 22a. It concluded that "the circumstances of this letter suggest that it merits a particularly low level of deference," *id.* 23a, noting that the letter was not shown to be the product of an agency proceeding, bore a "striking

resemblance" to the Covington & Burling memo, and had apparently been "formulated without the benefit of exposure to conflicting views or critiques," *id.* 24a; that the views in it were not expressed at the time of the purportedly preemptive actions or before Ms. Fellner's claims arose; that the views were "certainly not self-evident from the nature" of the purportedly preemptive actions and were ultimately expressed "only later, through a most informal of methods—a letter offering a legal theory for the litigation in California," *id.*; and that the reasoning of the letter was not persuasive. *Id.*

The court then turned to Tri-Union's specific conflict preemption theories. *Id.* 24a-35a. First, the court rejected Tri-Union's argument that Ms. Fellner's lawsuit conflicts with a federal regulatory scheme. The court explained that the FDA had not taken any action pertaining to mercury or mercury warnings that could be considered an exclusive application of federal law. Moreover, the court stated that even if the FDA's actions were of a type that could preempt state law, Tri-Union had identified no conflict between those actions and Ms. Fellner's claims. *Id.* 26a.

In particular, the court noted that the FDA had not acted to regulate, reiterating that "the letter itself does not establish a federal policy against warnings capable of preempting state law." *Id.* 29a. With regard to the Martek Petition Response, the court pointed out that it had not been asked to take judicial notice of the response and that it was therefore not clear that it could consider the response in the context of a motion to dismiss. It nonetheless addressed the response, explaining that it discussed mercury only briefly and in a different context, and that the FDA "merely explained that it would decline

to require that the omega-3 fatty acid health claim be accompanied by a mercury warning, not that all mercury warnings should be affirmatively prohibited." *Id.*

The Third Circuit next addressed Tri-Union's argument that Ms. Fellner's claims conflict with a federal decision not to regulate. The court reiterated that state law is not preempted by a mere decision by an agency not to act, and that it had found "no authority for the proposition that the FDA could institute a regime affirmatively proscribing all warning obligations via mere informal expressions of policy such as those found in the Commissioner's letter." *Id.* 30a. "[C]ourts have declined to permit agencies to promulgate express preemption decisions by informal letter." *Id.* 31a.

Finally, the court explained that Tri-Union's argument that the FDA would have deemed any tuna containing mercury warnings to be misbranded suffered "from the same shortcomings as its prior theories": Tri-Union had identified no regulatory actions through which the FDA established that a product containing mercury warnings was misbranded under federal law, *id.* 34a, and, in any event, had failed to identify an actual conflict between Ms. Fellner's claims and any FDA concerns. *Id.* 35a.

Having found "no federal law with which the alleged state duty to warn conflicts," the court reversed the district court's decision. *Id.* 36a. Tri-Union's petition for rehearing *en banc* was denied. *Id.* 55a-56a.

REASONS FOR DENYING THE WRIT

I. The Decision Below Is Consistent With *Dowhal* and This Court's Precedent.

1. Tri-Union claims that the decision below conflicts with *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910 (2004), because the California Supreme Court held that the letter at issue in that case "adopt[ed] a federal policy that preempted conflicting state law," while the Third Circuit held that the letter at issue here did not. Pet. 19. Not all letters are the same, however, and the letter at issue in *Dowhal* is not comparable to the letter in this case.[1]

The letter in *Dowhal* was the FDA's response to a citizen petition asking the FDA to require over-the-counter nicotine-replacement therapy (NRT) drug products to bear warnings similar to a warning it had approved for one NRT product. The FDA rejected the proposed warning, but set forth specific language for a revised warning. The California Supreme Court found that it was "apparent from the tenor of the letter that it imposes a duty on the defendants," *Dowhal*, 32 Cal. 4th at 927, and concluded that the letter was a "ruling" that "required" defendants to use the specific warning language and "prohibit[ed] defendants from giving consumers any warning other than the one approved by the FDA." *Id.* at 927-29.

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[1]Tri-Union implies that the Third Circuit might have been unaware of *Dowhal*, *see* Pet. 19, but Tri-Union cited *Dowhal* multiple times in its brief below and then filed a letter further discussing the case.

In contrast, the Commissioner's Letter here was not issued through one of the FDA's formal regulatory procedures and does not place any obligations on Tri-Union or anyone else. It is an informal letter to a party in litigation stating an opinion about preemption. And the Martek Petition Response—which Tri-Union cites in an attempt to find a relevant document issued through a recognized process—similarly imposes no legal obligation on Tri-Union. Simply put, unlike the *Dowhal* letter, which the court found prohibited the warnings the plaintiff sought, the Commissioner's Letter and Martek Petition Response neither require nor prohibit anything related to warnings. The Commissioner's Letter and *Dowhal* letter are not comparable in either formality or effect, and there is thus no conflict between *Dowhal* and the decision below.

In any event, this Court's recent decision in *Wyeth v. Levine* confirms that the Third Circuit was correct in not giving the Commissioner's Letter preemptive effect. In *Wyeth*, the Court differentiated between substantive federal law, which preempts conflicting state law, and "agency proclamations of pre-emption," which are not themselves preemptive, but are given deference in accordance with their thoroughness, consistency, and persuasiveness. Slip op. at 19-20 (citing *Mead*, 533 U.S. at 234-35, *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)). Here, the Commissioner's letter does not set forth substantive law, but rather "the agency's explanation of state law's impact on the federal scheme," *id.* at 20, and the court of appeals was correct to accord it deference only in proportion to its ability to persuade. *See* Pet. App. 23a (citing *Mead* and *Skidmore*).

2. Tri-Union also asserts that the Court should grant certiorari because the decision below is "inconsistent with this Court's precedent, which recognizes that agency actions need not rise to the level of formality that attends notice and comment procedures to carry preemptive force." Pet. 16; *see also id.* 21. Given that the Third Circuit specifically stated that "federal agency action . . . short of formal, notice and comment rulemaking may also have preemptive effect," Pet. App. 9a, this "inconsisten[cy]" is illusory.[2]

3. Finally, Tri-Union insists that the FDA has established an "authoritative policy against mercury warning labels," Pet. 21, that should be accorded preemptive effect. But Tri-Union's insistence does not make it so. The Consumer Advisory and backgrounder provide only non-binding advice on fish consumption to certain consumers; the Martek Petition Response "merely explained that [the FDA] would decline to require that the omega-3 fatty acid health claim be accompanied by a mercury warning, not that all mercury warnings should be affirmatively prohibited," Pet. App. 29a; and the Commissioner's Letter was not the product of any agency proceeding and is a "proclamation[] of pre-emption," *Wyeth*, slip op. at 19, not substantive law.

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[2]The Third Circuit's explanation that regularity of procedure could arise from rulemaking, adjudication, or "other [procedures]," Pet. App. 12a, makes clear that the court also did not hold, as Petitioner's amicus Chamber of Commerce claims, that agency action must be the result of either notice-and-comment rulemaking or adjudication to be preemptive.

Tri-Union points to a statement in *Arkansas Electric Cooperative Corp. v. Arksansas Public Service Commission*, 461 U.S. 375, 384 (1983), that "a federal decision to forgo regulation in a given area may imply an authoritative federal determination that the area is best left *un* regulated." Pet. 21. But this Court has specifically warned against drawing "exaggerated inferences" from the *Arkansas Electric Cooperative* statement and has rejected the argument that the statement allows preemption absent federal law. *Puerto Rico Dep't of Consumer Affairs v. Isla Petroleum Corp.*, 485 U.S. 495, 503 (1988). "There is no federal pre-emption in vacuo, without a constitutional text or a federal statute to assert it," *id.*, and the court of appeals was correct to hold that there is no preemption here.

II. The Decision Below Would Not Allow Tri-Union to Be Held Liable for Failing to Include a Warning That Would Violate Federal Law.

Tri-Union relies on the Commissioner's Letter to argue that the decision below would allow it to be held liable for failing to include warnings that would render its products misbranded under federal law. Although Congress provided the FDA with numerous ways of enforcing the statutory prohibition on misbranded food, however, sending an informal letter setting out a legal theory is not one of them. Moreover, the determination whether food is misbranded is not the FDA's to make. As the Court explained in *Wyeth v. Levine*, "because the statute contemplates that federal juries will resolve most misbranding claims, the FDA's belief that a [product] is misbranded is not conclusive." Slip op. at 13.

Contrary to Tri-Union's argument, the decision below does not conflict with *Grocery Manufacturers of America, Inc. v. Gerace*, 755 F.2d 993 (2d. Cir. 1985). Pet. 25. There, the FDA had promulgated a regulation defining imitation food. The court held that a New York law requiring cheese products that were not imitation under the FDA regulation to be labeled "imitation" was preempted because it would cause the food to be misbranded under federal law. In other words, the state law conflicted with substantive federal law enacted through regulation. Here, in contrast, the agency action is an informal letter, not a regulation, and it does not create substantive law, but rather states an opinion about what would make a product misbranded. *See Wyeth v. Levine*, slip op. at 13, 19-20.

Moreover, even if the Commissioner's Letter did carry the force of law, it still would not preempt the claims here. The letter pertained specifically to Proposition 65's safe-harbor warning and assumed that the required warning would be some version of "WARNING: This product contains a chemical known to the State of California to cause cancer" and "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm." It was these particular warnings—and no other—that the Commissioner said "omit facts which are necessary to place the information in its proper context." Ms. Fellner, however, has not claimed that Tri-Union should have used the Proposition 65 safe-harbor language, nor that it should have omitted other facts in warning consumers about mercury. Tri-Union jumps to the conclusion that because the Commissioner stated that the FDA would consider products with the Proposition 65 warnings to be

misbranded, it would consider any product that contained a mercury warning to be misbranded, but the Commissioner's Letter does not say that.

Finally, and most importantly, placing mercury warnings on tuna would *not* render them misbranded under the Food, Drug, and Cosmetic Act (FDCA). *See* 21 U.S.C. § 343(a)(1) (food is misbranded if its labeling is false or misleading). A mercury warning would be truthful, *see* Consumer Advisory (acknowledging that "nearly all fish" contains mercury, which can have "harmful effects"), and whether a label is misleading depends on how it would be perceived by consumers, who do not expect detailed scientific explanations on food labels or assume that foods with warnings lack benefits. Moreover, warnings could be crafted that describe both the products' benefits and the risks posed by mercury. And although Tri-Union notes that the Commissioner's Letter expresses a preference for advisories over warnings, the question here is not what the FDA prefers; it is whether tuna products with mercury warnings would be misbranded under the FDCA. They would not, and the court of appeals correctly held that Ms. Fellner's claims are not preempted.

III. This Court Has Reaffirmed the Presumption Against Preemption Twice Already This Term in Conflict Preemption Cases.

Earlier this month, in *Wyeth v. Levine*, this Court reiterated that the presumption against preemption applies "[i]n all pre-emption cases," and expressly rejected the argument that it does not apply to claims of implied conflict preemption. Slip op. at 8-9 & n.3; *see also Altria Group, Inc., v. Good*, 129 S. Ct. 538, 543 (2008)

(presumption against against preemption applies to "questions of express or implied pre-emption"). Thus, if there were any question at the time of the Third Circuit's decision about whether the presumption against preemption still applies to conflict preemption cases, that question has since been answered by this Court.

In any event, this case would not be an appropriate vehicle for considering the presumption against preemption because the presumption did not affect the outcome of the case below. Although the Third Circuit's decision includes an introductory section on the presumption, it does not mention or otherwise give any indication that it relied on the presumption in explaining why there is no conflict preemption here.[3] The court did not hold, for instance, that there might be a conflict, but the conflict was not sufficiently "clear and manifest" to overcome the presumption. *See, e.g., id.* at 543 (presumption can be overcome by "clear and manifest purpose of Congress") (citation omitted). Rather, it held that there was no conflict because FDA had not regulated mercury warnings to begin with. The court had no occasion to rely on a presumption that "the federal law should be read narrowly," Pet. 35, when there was no federal law for the court to read.

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[3]Indeed, the court of appeals relied far less on the presumption than this Court did in *California v. ARC America Corp.*, 490 U.S. 93, 101 (1989), and *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 716 (1985), two cases that Tri-Union attempts to explain away by asserting that they "did not reply on the presumption in [their] conflict preemption" analyses. Pet. 32.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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124

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IN THE

Supreme Court of the United States

TRI-UNION SEAFOODS, L.L.C.
D/B/A CHICKEN OF THE SEA,

Petitioner,

v.

DEBORAH FELLNER,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

REPLY TO BRIEF IN OPPOSITION

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TABLE OF CONTENTS

Page

REPLY TO BRIEF IN OPPOSITION.....1

CONCLUSION 12

TABLE OF AUTHORITIES

CASES

Page

Altria Group, Inc. v. *Good*, 129 S. Ct. 538 (2008) 9

Arkansas Electric Cooperative Corp. v. *Arkansas Public Service Commission*, 461 U.S. 375 (1983) 9

Dowhal v. *SmithKline Beecham Consumer Healthcare*, 88 P.3d 1 (2004) 1, 6, 7

Grocery Manufacturers of America, Inc. v. *Gerace*, 755 F.2d 993 (2d Cir. 1985) 10

Puerto Rico Department of Consumer Affairs v. *Isla Petroleum Corp.*, 485 U.S. 495 (1988) 9

Wyeth v. *Levine*, 173 L. Ed. 2d 51 (2009) 1, 7, 8, 10

STATUTES & REGULATORY MATERIALS

21 U.S.C. § 342 3

21 U.S.C. § 343 5

44 Fed. Reg. 3,990 (Jan. 19, 1979) 3

EPA-823-R-04-005 (March 2004) 3, 4, 5

REPLY TO BRIEF IN OPPOSITION

As demonstrated by the amicus briefs filed by the Chamber of Commerce of the United States of America and the National Fisheries Institute, the federal preemption issues raised in the Petition are important. The court of appeals determined that a series of actions by the Food and Drug Administration ("FDA") that reflect a considered regulatory policy against including warnings about the risks of methylmercury on tuna-product labels are insufficiently authoritative to preempt state law. Respondent's strained attempt to distinguish this case from *Dowhal* v. *SmithKline Beecham Consumer Healthcare*, in which the California Supreme Court held that a similar FDA policy was sufficiently "definite and authoritative" to preempt state law, only highlights the need for this Court's review. 88 P.3d 1, 9 (2004)

This Court's recent decision in *Wyeth* v. *Levine* does not "confirm[]" (Opp. 10) that the court of appeals' decision was correct. 555 U.S. __, 173 L. Ed. 2d 51 (2009). In *Wyeth*, this Court refused to accord deference to FDA's view, conveyed in a preamble to a regulation, that the respondent's tort claim was preempted, because FDA failed to provide interested parties "notice or opportunity for comment" and "reverse[d] [its] own longstanding position without providing a reasoned explanation." *Id.*, slip op. at 21. Here, by contrast, FDA's view that including warnings about the risk of methylmercury on tuna-product labels would frustrate its longstanding policy has been subject to notice and an opportunity to comment and is supported by a reasoned, consistent position. *Wyeth* therefore does not resolve the

important question whether FDA's longstanding and consistent policy against mercury warning labels on seafood products is sufficiently authoritative to preempt contrary state law.

Requiring warnings on tuna-product labels not only frustrates FDA's regulatory approach but also makes it impossible for petitioner to comply with both state and federal law. The court of appeals (Pet. App. 34a) and respondent (Opp. 12) dismiss this problem on the ground that FDA has not taken any enforcement action under its misbranding authority. But petitioner should not be required to wait until it has actually been subjected to liability where, as here, the federal policy is authoritative and the implications of complying with conflicting state requirements are clear.

Respondent's belief (Opp. 14) that some type of warning (other than the Proposition 65 warning that FDA squarely rejected) could be crafted that would not violate FDA's approach ignores the rationale for FDA's position in the California litigation. FDA explained that a warning purporting to convey factual information about the harms caused by methylmercury on a tuna-product label would be "misleading" because there is no "scientific basis as to the possible harm caused by [tuna products], or as to the amounts of such foods that would be required to cause this harm." Letter to Bill Lockyer, Attorney General of the State of California, http://www.cfsan.fda.gov/~dms/fl-ltr65.html. ("FDA Letter").

1. Respondent seeks to defend the court of appeals' decision by minimizing the role FDA has played in regulating methylmercury in seafood. Far

from having taken only a "few informal actions" (Opp. 1), however, FDA, pursuant to its statutory authority to regulate food products, has been addressing the issue for thirty years. In 1979, the FDA established an action level for the amount of mercury in seafood (1.0 part per million) and determined that seafood exceeding that threshold is subject to being treated as "adulterated" under 21 U.S.C. § 342. *See* 44 Fed. Reg. 3,990, 3,993 (Jan. 19, 1979). Since that time, FDA has studied methylmercury in seafood intensively and has taken a series of actions that reflect its considered judgment that consumer advisories rather than product-label warnings should be used to inform the public about the risks of methylmercury.

First, FDA issued an advisory on methylmercury in fish in 1995 in which it contrasted "eating a variety of types of fish, the normal pattern of consumption," which "does not put anyone in danger of mercury poisoning" with "fad diets—frequently eating only one type of food or a particular species of fish—"which place such dieters "at risk." C.A. App. A155.

Second, nine years later, FDA and the Environmental Protection Agency (EPA) issued a joint Advisory, which remains current, that emphasizes the health benefits of seafood and encourages "women and young children in particular" to "include fish or shellfish in their diets due to the many nutritional benefits." EPA-823-R-04-005, http://www.cfsan.fda.gov/~dms/admehg3.html (March 2004). The Advisory further explains that "[f]or most people, the risk from mercury by eating fish and shellfish is not a health concern." *Id.*

At the same time, the Advisory warns that "some fish and shellfish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system." *Id.* To address that risk, FDA and EPA provide detailed recommendations for women and young children, who are advised (1) not to eat certain fish that contain high levels of mercury (shark, swordfish, king mackerel, and tilefish); (2) to eat up to 12 ounces a week of a variety of fish and shellfish that are lower in mercury (including canned light tuna), or up to 6 ounces per week of albacore tuna; and (3) to eat no more than 6 ounces per week of fish caught by family or friends in local water in the absence of a local advisory providing specific advice. *See* Pet. 5-6.

Third, in September 2004, FDA, after providing notice and an opportunity to comment, rejected a petition filed by Martek Biosciences Corporation seeking to require that any qualified health claim concerning fish products, including tuna products, be accompanied by a statement warning of the possible harmful effects of mercury to pregnant women, women of childbearing age, nursing mothers, and young children.[1] In doing so, FDA explained that "the advisory approach" it has adopted "is more effective than a product label statement in relaying

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[1] Letter from William K. Hubbard, Assoc. Comm'r for Policy & Planning, FDA, to Martin J. Hahn, Hogan & Hartson, LLP (Sept. 8, 2004), http://www.fda.gov/ohrms/dockets/dockets/03q0401/03q-0401-ans0002-vol13.pdf ["FDA Martek Petition Denial"]; Letter from William K. Hubbard, Assoc. Comm'r for Policy & Planning, FDA, to Jonathan W. Emord, Emord & Associates, PC (Sept. 8, 2004), http://www.fda.gov/ohrms/dockets/dockets/03q0401/03q-0401-ans0001-vol13.pdf.

the complex messages about mercury in fish and shellfish." FDA Martek Petition Denial 28-29. Even more problematic, a product-label warning could cause "confusion" stemming from the different warnings that would accompany certain types of commercial fish on the one hand and locally caught fish on the other. *Id.* at 29. In addition, a warning on the product label could produce "unintended adverse public health consequences" by deterring non-vulnerable individuals from consuming fish products, which carry significant health benefits. *Id.*

Finally, consistent with the 2004 Advisory and Martek Petition Denial, the Commissioner of the FDA in August 2005 wrote a letter to the California Attorney General setting out FDA's position that a lawsuit seeking to require warnings about mercury on tuna-product labels under California's Proposition 65 was preempted by FDA's regulatory approach. FDA Letter. Citing the same concerns that led it to reject the Martek Petition, the Commissioner explained that FDA has "deliberately implemented its regulatory authority with a nuanced approach, relying primarily on disclosure of ingredient information and nutrition information on labels and, only under exceptional circumstances, requiring manufacturers to provide warnings on their labels." *Id.* at 6. With respect to methylmercury in fish products in particular, the Commissioner noted, FDA0020has adopted a "carefully considered approach of advising consumers of both the benefits and possible risks of eating seafood." *Id.* In FDA's view, the California lawsuit both "frustrate[s]" that approach and would render tuna products "misbranded" under federal law, 21 U.S.C. § 343,

because the proposed warnings "purport to convey factual information" about the risks of methylmercury "without any scientific basis as to the possible harm caused by [tuna products], or as to the amounts of [tuna products] that would be required to cause this harm." FDA Letter at 6.[2]

2. In the light of this longstanding and consistent FDA policy against including warnings about methylmercury on tuna-product labels, the court of appeals' holding that FDA's actions were too informal to be authoritative conflicts with *Dowhal*. In *Dowhal*, the California Supreme Court accorded preemptive effect to an FDA letter that rejected the plaintiff's citizen petition to the extent it sought to require a particular warning about the effects of nicotine-replacement-therapy (NRT) products on unborn children. Instead, the letter directed NRT manufacturers to use a warning that the agency had previously approved. The *Dowhal* court ruled that the FDA letter was sufficiently "definite and authoritative" to preempt state law, because "it is apparent from the tenor of the letter that it imposes a duty on defendants." 88 P.3d at 9-10.

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[2] Respondent (Opp. 4) seeks to impugn the integrity of the Commissioner's letter on the ground that it relied on a letter from counsel for the tuna industry defendants in the California litigation. A presumption of regularity attends agency action, however, and the agency was free to accept or reject the views of the tuna industry. Moreover, the Commissioner's letter relied on the reasoning of the Martek Petition Denial, which was issued after all interested parties had an opportunity to comment. *See* FDA Letter at 5-6 & n.7.

Respondent contends (Opp. 10) that the court of appeals' decision does not conflict with *Dowhal* because FDA's actions here imposed no duty on "[petitioner] or anyone else." Respondent is incorrect. It is equally "apparent from the tenor" of the Commissioner's Letter, the Martek Petition Denial, and the regulatory approach on which they are based, that federal law requires petitioner to refrain from adding to its tuna-products label a warning about the risks of methylmercury.[3]

Because FDA's policy against including warnings about methylmercury on seafood products is no less formal, authoritative, or definitive than FDA's denial of the citizen petition in *Dowhal*, there is a conflict between that decision and the decision below. Contrary to respondent's suggestion (Opp. 10), this Court's decision in *Wyeth* does not "confirm[]" that the court of appeals' decision was correct.

First, the Court in *Wyeth* held that the drug manufacturer failed to offer "clear evidence" that FDA would have rejected a change to Phenergan's label. *Wyeth*, slip op. at 15. Here, by contrast, there *is* clear evidence that FDA would reject a label warning about the risks of methylmercury in tuna products as antithetical to its "carefully considered approach." FDA Letter at 6.

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[3] Respondent contrasts (Opp. 10) the allegedly "informal" nature of the Commissioner's letter with the "formality" of the denial of the citizen petition in *Dowhal*. As noted above, however, the Commissioner's Letter relied heavily on the reasoned explanation that FDA provided in denying the Martek Petition, after notice and an opportunity for comment.

Second, this Court refused to defer to FDA's view that state tort law actions challenging labels approved by the FDA are preempted because that view was adopted "without offering States or other interested parties notice or opportunity for comment" and because the view "reverse[d] the FDA's own longstanding position without providing a reasoned explanation." *Wyeth*, slip op. at 21. Here, by contrast, FDA's deliberate decision to regulate methylmercury through consumer advisories rather than warnings was subject to notice and an opportunity to comment. *See* Martek Petition Denial.

In that formal process, FDA set out its rationale for that approach, including its view that consumer advisories are "more effective than a product label statement in relaying the complex messages about mercury in fish and shellfish"; warnings would not contain the "level of clarity and detail" that advisories contain; warnings would cause "confusion"; and "a label statement that reaches the public at large can . . . have unintended adverse public health consequences." Martek Petition Denial 28-29. The Commissioner's Letter, in which he articulated FDA's view that Proposition 65 warnings were preempted, was a logical extension of the Martek Petition Denial, which had explained why warnings would undermine the FDA's regulatory approach. As such, it is entitled to more deference than the "inherently suspect" agency views in *Wyeth*, slip op. at 21. The decision in *Wyeth* therefore does not eliminate the need for review of the court of appeals' decision, which refused to accord preemptive effect to FDA's longstanding and consistent policy

against warnings about methylmercury on tuna-product labels.

Contrary to respondent's suggestion (Opp. 12), petitioner is not asking this Court to draw "exaggerated inferences" from its statement in *Arkansas Electric Cooperative Corp.* v. *Arkansas Public Service Commission*, 461 U.S. 375, 384 (1983), that "a federal decision to forgo regulation in a given area may imply an authoritative federal determination that the area is best left *un*regulated." Indeed, the Court need not go as far as that basic proposition would permit. Here, FDA has made its policy against warnings explicit. FDA has not merely forgone requiring warnings; it has explained why warnings would undercut its regulatory approach.

This case is thus a far cry from *Puerto Rico Department of Consumer Affairs* v. *Isla Petroleum Corp.*, 485 U.S. 495 (1988) (cited at Opp. 12), where the Court declined to find that certain gasoline price regulations were preempted in "the absence of *any extant federal regulatory program with which the state regulation might conflict.*" *Id.* at 500 (emphasis added). It is clear that FDA has a regulatory policy governing methylmercury in seafood. It is also clear that FDA's policy will not countenance warnings about methylmercury on tuna-product labels. The only question is whether that policy is sufficiently authoritative to carry preemptive force, and that question merits this Court's review. *See* Brief of the Chamber of Commerce of the United States of America as *Amicus Curiae* in Support of Petitioner, *Tri-Union Seafoods, L.L.C.* v. *Fellner*, No. 08-889, at 20-22 (noting that in *Altria Group, Inc.* v. *Good*, 129

S. Ct. 538 (2008), this Court granted review of question whether "the agency's action was too 'informal' to preempt conflicting state law" but ultimately found it unnecessary to resolve that question).

3. This Court should grant review for the additional reason that the court of appeals' decision places petitioner in the untenable position of facing exposure to state tort liability as the price for complying with federal law. Respondent downplays petitioner's predicament, pointing out that FDA has not "enforce[ed] the statutory prohibition on misbranded food." Opp. 12. But petitioner has not given FDA a reason to do so because it has complied with FDA's policy against including warnings about methyl-mercury on its tuna-product labels. Moreover, state law is preempted when it is "impossible for [the regulated party] to comply with both federal and state requirements." *Wyeth*, slip op. at 15. It has never been the rule that a party must suffer federal penalties to establish what federal law requires.

Respondent contends (Opp. 13) that the court of appeals' decision does not conflict with *Grocery Manufacturers of America, Inc.* v. *Gerace*, 755 F.2d 993 (2d Cir. 1985), because the federal requirement there arose from a regulation rather than "an informal letter." As explained above, the federal prohibition of warnings about methylmercury on tuna-product labels arises not merely from the Commissioner's letter, which reflects a culmination of FDA's preexisting policy. In any event, respondent's assertion that FDA's policy is insufficiently authoritative implicates the conflict

between the court of appeals' decision and *Dowhal*, which merits this Court's review.

Finally, respondent contends (Opp. 14) that, even if the FDA Letter carries the force of law, a warning other than the Proposition 65 warning that FDA rejected "could be crafted" that would not render tuna products misbranded under federal law. Respondent's position ignores the rationale for FDA's policy. As the Commissioner explained, FDA has chosen consumer advisories rather than product-label warnings to inform the public about the risks of methylmercury, because, among other reasons, a general warning could have "adverse public health consequences," including deterring non-vulnerable individuals from eating fish and obtaining the attendant health benefits. FDA Letter at 2-3. Moreover, a warning purporting to convey specific factual information about the harm caused by methylmercury (*e.g.*, that it "is known to cause cancer and reproductive harm," *id.* at 6) would lack "any scientific basis as to the possible harm caused by [tuna products], or as to the amounts of such foods that would be required to cause this harm." *Id.* at 6. Respondent's speculation that some type of warning could circumvent these concerns is unpersuasive.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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122

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In the Supreme Court of the United States

TRI-UNION SEAFOODS, L.L.C.,
D/B/A CHICKEN OF THE SEA,

Petitioner,

v.

DEBORAH FELLNER,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES. iii

INTEREST OF THE *AMICUS CURIAE*. 1

STATEMENT. 2

INTRODUCTION AND SUMMARY OF ARGUMENT. 6

ARGUMENT. 8

I. THIS COURT SHOULD DECIDE WHETHER THE PRESUMPTION AGAINST PREEMPTION APPLIES TO CONFLICT PREEMPTION. 8

A. The Decision Below Deepens A Circuit Split And Departs From This Court's Methodology In Recent Conflict Preemption Cases. 8

B. The Issue Arises At The Threshold Of Every Conflict Preemption Case. 11

C. The Use Of A Presumption In This Setting Is Contrary To The Supremacy Clause. 12

TABLE OF CONTENTS — cont'd

Page

II. THE COURT SHOULD ALSO DECIDE WHETHER AGENCY ACTIONS OTHER THAN ADJUDICATION AND RULEMAKING CAN PREEMPT STATE LAW, AN ISSUE GRANTED BUT NOT REACHED IN *ALTRIA* v. *GOOD*. 16

A. The Decision Below Squarely Conflicts With A Decision Of The California Supreme Court And Deepens The Confusion In The Circuits. 16

B. The Third Circuit's Restrictive View of Preemptive Agency Action Is Inconsistent With Several Lines Of This Court's Decisions.. 17

C. This Court Granted Review Of This Issue But Did Not Resolve It In *Altria* v. *Good*.. 20

CONCLUSION. 22

TABLE OF AUTHORITIES

Page(s)

Cases:

Altria Group, Inc. v. *Good*,
129 S. Ct. 538 (2008).. . . . . *passim*

American Tel. & Tel. Co. v. *Central Office Equipment, Inc.*, 524 U.S. 214 (1998). 18

Arkansas Elec. Coop. Corp. v. *Arkansas Public Serv. Comm'n*, 461 U.S. 375 (1983).. 19

Arkansas Louisiana Gas Co. v. *Hall*, 453 U.S. 571 (1981).. 18

Buckman Co. v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).. 13

Cipollone v. *Liggett Group, Inc.*, 505 U.S. 504 (1992).. . . . . 2, 14

Crosby v *Nat'l Foreign Trade Council*, 530 U.S. 363 (2000).. . . . . 9, 15

Desiano v. *Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006). 12

Dowhal v. *SmithKline Beecham Consumer Healthcare*, 88 P.3d 1 (Cal. 2004).. . . . . 7, 16

English v. *Gen. Elec. Co.*, 496 U.S. 72 (1990). 14

TABLE OF AUTHORITIES — cont'd

Page(s)

Exxon Shipping Co. v. *Baker*,
128 S. Ct. 2605 (2008).. 12

Feikema v. *Texaco, Inc.*,
16 F.3d 1408 (4th Cir. 1994). 17

Fidelity Sav. & Loan Ass'n v. *de la Cuesta*,
458 U.S. 141 (1982).. 14

Florida State Conference of the NAACP v.
Browning, 522 F.3d 1153
(11th Cir. 2008).. 13

Geier v. *American Honda Co.*,
529 U.S. 861 (2000).. 14

General Motors Corp. v. *Abrams*,
897 F.2d 34 (2d Cir. 1990). 17

Gibbons v. *Ogden*, 22 U.S. (9 Wheat.) (1824).. 2

Good v. *Altria Group, Inc.*,
501 F.3d 29 (1st Cir. 2007). 7, 20

Hillsborough County v. *Automated Med. Labs., Inc.*,
471 U.S. 707 (1985).. 10

Houston v. *Moore*, 18 U.S. (5 Wheat.) (1820). 2

Irving v. *Mazda Motor Corp.*,
136 F.3d 764 (11th Cir. 1998). 9

M'Culloch v. *Maryland*,
17 U.S. (4 Wheat.) 316 (1819). 2

TABLE OF AUTHORITIES — cont'd

Page(s)

Medtronic, Inc. v. *Lohr*,
518 U.S. 470 (1996).. . . . . 10, 14

New York v. *United States*,
505 U.S. 144 (1992).. 3

Perry v. *Mercedes Benz N. Am. Inc.*,
957 F.2d 1257 (5th Cir. 1992). 9

Rice v. *Santa Fe Elevator Corp.*,
331 U.S. 218 (1947).. 9

Riegel v. *Medtronic*, 128 S. Ct. 999 (2008). 10, 18

Sprietsma v. *Mercury Marine*,
537 U.S. 51 (2002). 19

Warner-Lambert Co. v. *Kent*,
128 S. Ct. 1168 (2008).. 11

Constitutional Provision, Statutes, and Regulation:

U.S. CONST. art. VI, cl. 2 . . . . . 2, 12

21 U.S.C. § 333(a)(1).. 20

21 U.S.C. § 334. 20

21 U.S.C. § 343. 20

TABLE OF AUTHORITIES — cont'd

Page(s)

Egg Products Inspection Act,
21 U.S.C. § 1052. 4

Federal Meat Inspection Act,
21 U.S.C. § 678. 4

Food, Drug, and Cosmetic Act, 21 U.S.C.
§§ 301 *et seq.* 3

Nutritional Education and Labeling Act,
21 U.S.C. § 343-1. 3

Poultry Products Inspection Act,
21 U.S.C. § 467e. 4

21 C.F.R. § 10.40. 18

Miscellaneous:

Viet Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085 (2000). 13

Jack Goldsmith, *Statutory Foreign Affairs Preemption*, 2000 S. CT. REV. 175. 13

Caleb Nelson, *Preemption*,
86 VA. L. REV. 225 (2000). 12, 13

U.S. CENSUS BUREAU, STATISTICAL ABSTRACT OF THE UNITED STATES (2004). 3

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF THE *AMICUS CURIAE*[1]

The Chamber of Commerce of the United States of America (the Chamber) is the world's largest business federation. The Chamber represents an underlying membership of more than three million companies and professional organizations of every size, in every industry, from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases that raise issues of vital concern to the Nation's business community.

This is such a case. The Chamber's members include millions of businesses that are subject to preemptive federal statutes, regulations, and agency actions. These businesses depend on a robust doctrine of implied preemption as protection against state and local mandates that conflict with federal requirements (including, as in this case, requirements that happen to

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[1] Counsel of record for all parties received timely notice of the *amicus curiae*'s intent to file this brief. S. Ct. Rule 37.2(a). The parties' letters of consent to the filing of this brief have been filed with the Clerk. Under Rule 37.6 of the Rules of this Court, *amicus curiae* states that no counsel for a party has authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than the *amicus curiae*, its members, or its counsel, has made a monetary contribution to this brief's preparation or submission.

be expressed, unambiguously and authoritatively, by an expert administrative agency *outside of* the pages of the Code of Federal Regulation). The Supremacy Clause of the Constitution, which is the fountainhead of the doctrine of implied conflict preemption, serves a vital structural role in our Nation's government by protecting federal laws, programs, policies and prerogatives against encroachment and interference by subordinate governments (including interference by state tort law as applied by lay juries). The Supremacy Clause also helps to create unified markets for nationally distributed goods and services. Further review is needed to clarify several significant issues of preemption law that are raised by the petition. Accordingly, the Chamber and its members have a substantial interest in ensuring that this Court grant the petition and correct the serious errors made by the lower court.

STATEMENT

1. The Supremacy Clause provides that the Constitution and federal laws and treaties "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby; any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2. This Court's decisions interpreting the Supremacy Clause – and articulating what has come to be known as the doctrine of implied conflict preemption – stretch back to the earliest days of the Republic. See, *e.g.*, *Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1 (1824); *Houston* v. *Moore*, 18 U.S. (5 Wheat.) 1 (1820); *M'Culloch* v. *Maryland*, 17 U.S. (4 Wheat.) 316 (1819). "[S]ince our decision in *M'Culloch*," the Court has explained, "it has been settled that state law that conflicts with federal law is 'without effect.'" *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 516 (1992).

During the last century (and particularly since the New Deal), in response to fundamental changes in the national economy, there has been a significant expansion of federal law and of the activities of the national government. This includes Congress's creation of dozens of expert, specialized administrative agencies to oversee – and often to comprehensively regulate – complex and important facets of the economy. By virtue of the Supremacy Clause, the inevitable consequence of this expansion of federal authority has been to increase the likelihood of conflicts with the laws and regulatory efforts of state and municipal governments. *New York* v. *United States*, 505 U.S. 144, 159 (1992) ("As the Federal Government's willingness to exercise power within the confines of the Constitution has grown, the authority of the States has correspondingly diminished to the extent that federal and state policies have conflicted."). The risk of conflict is further enhanced by the existence, at last count, of approximately 87,525 local governmental units in the United States, including more than 3,000 counties, more than 19,000 municipalities, and more than 16,000 towns or townships. U.S. CENSUS BUREAU, STATISTICAL ABSTRACT OF THE UNITED STATES 262 (2004). It should come as no surprise that issues of conflict preemption arise with great frequency today.

2. This case arises against the backdrop of longstanding regulation by the Food and Drug Administration (FDA) of food safety under the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, as amended, and, more specifically, of the health risks associated with methylmercury in fish.[2] As petitioners demonstrate

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[2] In the area of food safety, Congress has often used preemption clauses to ensure national uniformity of federal regulation. Examples include the Nutritional Education and Labeling Act, 21

(Pet. 4-11), for more than a decade the FDA has carefully examined the scientific data concerning the risks of human consumption of methylmercury in fish and, on the basis of that analysis (as well as the agency's study through focus groups of the effect of various communications on consumers), has devised a balanced and nuanced regulatory program aimed at informing consumers of those risks. In particular, the FDA has undertaken to balance comprehensively the societal health benefits of eating fish (which might be reduced by warnings aimed in blunderbuss fashion at the general population) against the potential risks to specific subgroups of consumers, including nursing mothers, pregnant women, and young children (risks that FDA has concluded can and should be conveyed through more targeted communications). Because of its scientific and public-health expertise, the FDA is uniquely qualified to make these delicate judgments.

Congress has armed the agency with broad authority to act in a wide variety of ways, both formal and informal, to carry out the agency's responsibility of protecting the public health. Over the years, the FDA has carried out its extensive and balanced program concerning methylmercury in fish through a series of regulatory actions, including (1) the issuance of consumer advisories; (2) the denial of a "citizen" petition submitted by Martek Biosciences Corporation, which had requested that FDA mandate that qualified health claims relating to the health benefits of consuming

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U.S.C. § 343-1, the Poultry Products Inspection Act, *id.* § 467e, the Federal Meat Inspection Act, *id.* § 678, and the Egg Products Inspection Act, *id.* § 1052. Even where no express preemption clause applies, Congress legislates – and administrative agencies regulate – against the backdrop of ordinary principles of implied conflict preemption.

omega-3 fatty acids be accompanied, in the case of fish products, with additional mercury-related warnings; and (3) the FDA Commissioner's issuance of a letter to the California Attorney General making clear that certain warnings sought by the latter in litigation under California law would be impossible for manufacturers to provide without violating the FDA's requirements and rendering products "misbranded" in violation of federal law.

3. Respondent filed this lawsuit in New Jersey state court, alleging among other things that petitioner, which manufactures Chicken-of-the-Sea tuna products, violated several New Jersey statutes by committing fraud and by failing to provide adequate warnings of the risks of mercury consumption. In respondent's view, New Jersey law imposed a duty to warn of the hazards that might arise if someone (such as respondent) elected to follow a "fad" diet of eating only (or mostly) canned tuna fish for years on end. After petitioner removed the case to federal court, the district court granted petitioner's motion to dismiss on the ground that respondent's statutory claims were preempted by federal law. See also Pet. 13 n.4. Citing the "FDA's ten-year deliberately balanced approach to the issue of methylmercury in fish," the district court explained that "it would be impossible for [petitioner] to comply with the FDA" as well as with "New Jersey law." Pet. App. 52a-53a.

The Third Circuit reversed. Pet. App. 1a-37a. As a threshold matter, it ruled that a "presumption against preemption" was applicable here because, notwithstanding the FDA's longstanding regulatory activities concerning mercury in fish, respondent's "tort-like action" falls "squarely within the realm of traditional state regulation." *Id.* at 19a. Although acknowledging that the Supreme Court "has applied the presumption in few

conflict preemption cases of late," the Third Circuit declared its intent to continue to apply that presumption in conflict preemption cases "until the Supreme Court provides guidance to the contrary." *Id.* at 21a. Applying the presumption, the court of appeals proceeded to reject the preemption defense, reasoning that the FDA's various regulatory actions – including the FDA Commissioner's letter to the California Attorney General – were not sufficiently "formal" to give rise to preemption of state law. *Id.* at 11a-24a.

INTRODUCTION AND SUMMARY OF ARGUMENT

The petition in this case squarely and cleanly raises two issues of federal preemption law that are of surpassing doctrinal and practical importance. Both issues are recurring and have produced significant disagreements in the lower courts – conflicts that only this Court can resolve. The Third Circuit decided both issues incorrectly, and its rulings are inconsistent with the results and analysis in some of this Court's own decisions. Ordinarily this would be more than enough to justify further review by this Court. But here there is even more reason to grant the petition.

As the Third Circuit correctly noted in applying the presumption against preemption over petitioners' objections (and in conflict with decisions of two other circuits, see Pet. 29-31), this Court in recent years "has applied the presumption in few conflict preemption cases." Pet. App. 21a. Despite this Court's recent practice of *not* relying on the presumption in conflict preemption cases, and the existence of various good arguments for why "the conflict preemption analysis subsumes or supplants the presumption," *ibid.*, the Third Circuit declined to examine the validity of the

presumption in this setting. "[W]e will continue," the court instead declared, "to apply the traditional presumption *until the Supreme Court provides guidance to the contrary*." *Ibid.* (emphasis added). Further review is especially warranted to provide that needed guidance not only because this Court's *own decisions* are the source of confusion but also because the Third Circuit has declared an unwillingness to follow this Court's example in recent conflict preemption cases. Moreover, this issue arises at the threshold of *every* conflict preemption case. It deserves a clear answer, which only this Court can provide.

There are additional reasons for granting review of the other issue raised by the petition as well. Just last Term, in *Altria Group, Inc.* v. *Good*, 129 S. Ct. 538 (2008), this Court granted review of an implied preemption issue that included whether an administrative agency's policy that was not embodied or reflected in a formal regulation (but rather only in less formal agency actions) could trigger implied preemption. See No. 07-562 Pet. i, 20-24. In *Good*, the First Circuit had rejected the conflict preemption defense in part because the Federal Trade Commission (FTC) "has never issued a formal rule specifically defining which cigarette advertising practices violate the [Food, Drug and Cosmetic] Act." *Good* v. *Altria Group, Inc.*, 501 F.3d 29, 51 (1st Cir. 2007). At the same time, the First Circuit acknowledged that "[o]ther courts . . . have held that an agency *can* preempt state law through action short of formal rulemaking." *Ibid.* (emphasis added) (citing the decisions of several federal courts of appeal as well as *Dowhal* v. *SmithKline Beecham Consumer Healthcare*, 88 P.3d 1 (Cal. 2004)). This Court granted review to resolve that disagreement even though there was no

conflict in the "light" cigarette cases over the validity of the implied preemption defense.

Because this Court's decision in *Good* resolved the implied preemption issue on other grounds (the nonexistence of any FTC policy), the broader doctrinal conflict identified in the *Good* petition persists. Indeed, the Third Circuit's decision in this case significantly compounds the confusion because it creates a direct conflict with the California Supreme Court's decision in *Dowhal*, a case cited by the First Circuit and by the certiorari petition in *Good*, over whether an FDA letter can trigger conflict preemption. As just explained, this Court has *already* determined that the agency preemption issue raised in this case warrants further consideration. And the reasons for granting review have become only more persuasive since the petition was granted in *Good*. The Court should take this opportunity to address an issue that is of utmost importance to regulated entities.

ARGUMENT

I. THIS COURT SHOULD DECIDE WHETHER THE PRESUMPTION AGAINST PREEMPTION APPLIES TO CONFLICT PREEMPTION

A. The Decision Below Deepens A Circuit Split And Departs From This Court's Methodology In Recent Conflict Preemption Cases

The Third Circuit parted company with the Fifth and Eleventh Circuits when it applied a "presumption against preemption" in this case. The lower court held that the presumption applies across-the-board to *all* preemption cases, including those involving the defense of implied conflict preemption. See Pet. App. 18a-21a. The Fifth and Eleventh Circuits have reached exactly the opposite view, ruling that the presumption is

irrelevant to the analysis of potential conflicts between state and federal law. See *Perry* v. *Mercedes Benz N. Am., Inc.*, 957 F.2d 1257, 1261-62 (5th Cir. 1992) ("We do not begin with an assumption against conflict preemption."); *Irving* v. *Mazda Motor Corp.*, 136 F.3d 764, 769 (11th Cir. 1998) ("When considering implied preemption, no presumption exists against preemption."); see also Pet. 29-31. This clear rift in the circuits warrants this Court's review.

Moreover, the Third Circuit's decision reflects the widespread confusion in the lower courts about critical aspects of *this Court's* conflict preemption jurisprudence. As the lower court candidly acknowledged (Pet. App. 21a), its decision to apply the presumption strays from the vast majority of this Court's recent conflict preemption decisions, which make no mention of the presumption. See also Pet. 32 (identifying such cases). The confusion in the lower courts about where this Court stands is also compounded by *Crosby* v. *Nat'l Foreign Trade Council*, 530 U.S. 363 (2000), in which this Court said it was "leav[ing]" the consideration of this issue "for another day." *Id.* at 374 n.8.[3]

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[3] This Court's recent 5-4 decision in *Altria Group, Inc.* v. *Good*, 129 S. Ct. 538 (2008), is unlikely to dispel the confusion in the lower courts – and may even exacerbate it. On the one hand, the majority opinion states, albeit only in passing, that "[w]hen addressing questions of express *or implied* pre-emption, we begin our analysis 'with the assumption that the historic police powers of the States [are] not superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Id.* at 543 (emphasis added) (quoting *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). On the other hand, the majority's rejection of Altria's implied conflict preemption arguments later in the opinion does not invoke or in any way rely upon any such "assumption." Beyond that, the four dissenting Justices in *Good* criticized the majority for applying the presumption to the *express* preemption issue before the Court, arguing that the majority's

Without a clear resolution to this important issue, some lower courts have seized on snippets of language in a few of this Court's decisions to find support for applying the presumption. In this case, for example, the Third Circuit invoked one of the rare conflict preemption decisions where this Court mentioned (but did not rely on) the presumption. See Pet. App. 21a (citing *Hillsborough County* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985)); see also Pet. 32 n.14. The lower court also quoted a passage from *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996) – an *express* preemption case – which appeared to suggest that the presumption applies in "all" preemption cases. See Pet. App. 18a-19a (quoting 518 U.S. at 485). Insofar as such dicta have sown confusion and provided daylight for the proponents of the presumption, this merely underscores the need for this Court finally to address the issue and provide clarification to the lower courts.

Without such clarification, there is no doubt that the lower courts will remain hopelessly divided on this issue. The court of appeals recognized that "arguments have been raised that the conflict preemption analysis subsumes or supplants the presumption," but declined even to consider those arguments and declared that it would continue reflexively to apply the presumption

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analysis was impossible to reconcile with *Riegel* v. *Medtronic*, 128 S. Ct. 999 (2008), but made no mention of the majority's dicta concerning the presumption's use in implied preemption cases. See *Good*, 129 S. Ct. at 555-58 (dissenting opinion). The majority in *Good* did not explain how *Riegel* and *Good* could be reconciled, nor did it address the recent scholarship (brought to this Court's attention in several recent cases by the Chamber and other business *amici*, see pages 11-15, *infra*), which demonstrates, based on newly uncovered historical evidence, that a presumption against preemption *in any setting* is inconsistent with the clear historical understanding of the Supremacy Clause.

"until the Supreme Court provides guidance to the contrary." Pet. App. 21a. Given the split among the circuits and evident confusion about the meaning of its past decisions, this Court should wait no longer to provide the much-needed clarification.

B. The Issue Arises At The Threshold Of Every Conflict Preemption Case

As the scope of the federal government's activities has grown, so too have opportunities for conflicts between state and federal authority. New federal statutes and regulatory activity frequently generate conflicts with state and local law, requiring the courts to resolve issues of conflict preemption. In each case involving a claim of conflict preemption, a court must as a threshold matter face the very question that has so sharply divided the circuits: Does the analysis begin with a judicial thumb on the scales *against* a finding of conflict preemption?

Given the increasing frequency with which the courts must face this question, and the importance of its answer for millions of businesses and individuals regulated at both the state and federal levels, it is no surprise that the Chamber and other national business groups have filed *amicus* briefs in many of this Court's recent cases criticizing the presumption against preemption on multiple grounds. See, *e.g.*, Chamber Br., *Watters* v. *Wachovia Bank*, No. 05-1342, 2006 WL 3203256, at *10-14; Br. of the Product Liability Advisory Council, Inc., and the Chamber, *United States* v. *Locke*, Nos. 98-1701 and 98-1706, 1999 WL 966527, at *4-12; Chamber Br., *Geier* v. *Am. Honda Motor Co.*, No. 98-1811, 1999 WL 1049891, at *25-26.

In *Warner-Lambert Co.* v. *Kent*, 128 S. Ct. 1168 (2008), the Chamber recently argued at length that the presumption is categorically inapplicable to conflict

preemption cases. See No. 06-1498 Chamber Br., 2007 WL 4205141, at *8-20. In *Warner-Lambert*, the Second Circuit had relied heavily on the presumption in holding that federal law did not impliedly preempt a Michigan statute. See *Desiano* v. *Warner-Lambert & Co.*, 467 F.3d 85 (2006). This Court granted review but affirmed by an equally divided court, 128 S. Ct. 1168, thus leaving the issue unresolved. See *Exxon Shipping Co.* v. *Baker*, 128 S. Ct. 2605, 2616 (2008) (explaining that such a disposition "is not precedential"). This case presents another, excellent opportunity to resolve this important and recurring question.[4]

C. The Use Of A Presumption In This Setting Is Contrary To The Supremacy Clause

The text of the Constitution provides no basis – none – for applying a presumption against preemption in any circumstance. Indeed, it points in exactly the opposite direction. A fundamental principle of the Constitution is that Congress may legislate preemptively pursuant to its enumerated powers, and federal law "shall be the supreme Law of the Land . . . *any* Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2 (emphasis added). As scholars have persuasively demonstrated, eighteenth century lawyers and judges would have recognized the concluding phrase of the Supremacy Clause as a "*non obstante*" provision "telling courts *not* to apply the traditional presumption against implied repeals in determining whether federal law contradicts state law." Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 255 (2000) (emphasis added); see also

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[4] More recently, the Chamber also addressed this issue in its brief as *amicus curiae* in *Wyeth* v. *Levine*, No. 06-1249 (oral argument held on November 3, 2008). See No. 06-1249 Chamber Br. 27-28.

Jack Goldsmith, *Statutory Foreign Affairs Preemption*, 2000 S. CT. REV. 175, 182, 184 (arguing that "the Supremacy Clause's *non obstante* clause . . . was designed precisely to eliminate any residual presumption" against implied repeals).

By its very nature, the Supremacy Clause thus directs courts to avoid precisely the evil that a presumption *against* preemption introduces: that they "might strain the federal law's meaning in order to harmonize it with state law." Nelson, 86 VA. L. REV. at 255; see also Viet Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2092 (2000) (explaining that any "systemic favor[ing]" of state law in analyzing preemption questions "risk[s] an illegitimate expansion of the judicial function" by "disrupt[ing] the constitutional division of power between federal and state governments, rewrit[ing] the laws enacted by Congress, or both"). As the Eleventh Circuit explained in declining to apply the presumption in a conflict preemption case,"[f]ederal law is not obligated to bend over backwards to accommodate contradictory state laws, as should be clear from the Supremacy Clause's blanket instruction." *Florida State Conference of the NAACP* v. *Browning*, 522 F.3d 1153, 1168 (2008); see also Pet. 30. Placing a thumb on the scale in favor of state law over federal law is precisely opposite to the approach dictated by the Supremacy Clause's text.

Implied conflict preemption cases are a *particularly* strange place to apply a presumption against preemption. The presumption is typically – though controversially – articulated as a safeguard against too lightly inferring that Congress *intended* to preempt state law in an area of *traditional state regulation*. See *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-48 (2001). But where an actual conflict exists between

state and federal law, it is simply irrelevant that the offending state law falls within an area of traditional state authority. See *Fidelity Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982) ("The relative importance to the State of its own law is not material when there is a conflict with a valid federal law, for the Framers of our Constitution provided that the federal law must prevail.") (internal quotation marks omitted). By the same token, where federal and state law stand in direct conflict, no inference about Congress's preemptive intent is necessary. Indeed, Congress acts against the backdrop of the well-settled assumption that its handiwork preempts any and all conflicting state law.

In this regard, "conflict pre-emption is different," *Geier* v. *American Honda Co.*, 529 U.S. 861, 884 (2000), from express and implied *field* preemption. In express preemption cases, courts look to the text of an express preemption clause and infer from it the scope of Congress's preemptive intent. See *English* v. *Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). Likewise, in implied field preemption cases the substantive provisions of federal law must support an inference that Congress intended federal law to occupy a given field. See *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 517 (1992). Regardless of whether the presumption against preemption applies where courts must infer Congress's intent, it is entirely inapplicable to the determination of whether state and federal laws stand in conflict with each other. Cf. *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 504 (1996) (Breyer, J.) (explaining that conflict preemption is possible "[w]here Congress likely did not focus specifically on the matter"). That is a question not of Congress's preemptive intent but rather of the Supremacy Clause's meaning. And where such conflicts between federal and state law do exist, any "federalism concerns," *Lohr*, 518 U.S. at 485, that arguably might be

invoked as a justification for the "presumption against preemption" already have been conclusively resolved – by the Supremacy Clause.

* * * * *

In *Crosby*, this Court left "for another day" consideration of whether a presumption against preemption applies to conflict preemption. 530 U.S. at 374 n.8. That day has arrived. This case presents an excellent vehicle for the Court to finally answer this important and recurring question of constitutional law – one that intractably divides the courts of appeals and is implicated in every case that presents a conflict between expanding federal laws and regulatory activities and proliferating state and local regulation. Beyond that, the time really has come for this Court to address head on the detailed historical critique of the presumption against preemption that has been so carefully developed in recent years by Caleb Nelson, Jack Goldsmith, and Viet Dinh, not to mention other legal scholars. The alternative of invoking the presumption in some cases but ignoring it in others – and doing so in the face of, but without ever responding to, vigorous dissenting opinions that accuse the Court of methodological inconsistency (see note 3, *supra*) – has the effect of sowing more confusion in the lower courts and creating the impression that this Court is more concerned about outcomes in individual cases than about articulating and applying a consistent methodology that would promote the rule of law.

II. THIS COURT SHOULD DECIDE WHETHER AGENCY ACTIONS OTHER THAN ADJUDICATION AND RULEMAKING CAN PREEMPT STATE LAW, AN ISSUE GRANTED BUT NOT REACHED IN *ALTRIA* v. *GOOD*

A. The Decision Below Squarely Conflicts With A Decision Of The California Supreme Court And Deepens The Confusion In The Circuits

In *Dowhal* v. *SmithKline Beecham Consumer Healthcare*, 88 P.3d 1, 11 (2004), the California Supreme Court unanimously held that (1) the FDA prohibited nicotine replacement therapy products from bearing any warnings other than those approved by the agency, and (2) the FDA's policy preempted a claim that state law required those products to carry different warnings. In reaching these conclusions, *Dowhal* specifically rejected the position adopted by the Third Circuit in this case: that the FDA's regulation of product warnings, as articulated in a letter from the FDA Commissioner, could not preempt contrary state law because that letter was not the product of a full-blown rulemaking or adjudicatory proceeding. *Id.* at 9-11. In *Dowhal*, the California Supreme Court held that because the FDA had demonstrated a clear and "sufficiently definite" federal policy through its letter, within a regulatory arena entrusted to it by Congress, the agency's policy preempted conflicting state law. *Ibid.*

In stark contrast, the Third Circuit declined to "afford preemptive effect" to any "less formal measures" than an agency's notice-and-comment rulemaking or adjudication. Pet. App. 12a. In taking a far more restrictive view of agency preemption, the lower court denied any preemptive force to the FDA's comprehensive and balanced approach to fish product labeling as expressed through (1) detailed consumer advisories

addressing the risks posed by mercury in fish, see Pet. 5-6, (2) the FDA's rejection – after public comment – of a petition that sought to require additional mercury-related warnings, see *id.* at 6-8, and (3) a letter written by the FDA Commissioner that explained how additional state-law warning requirements would "frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish," *id.* at 12 (quoting FDA Commissioner's letter ("FDA Preemption Letter")); see also *id.* at 9-12. In the Third Circuit's view, these regulatory activities cannot, either singly or in combination, impliedly preempt state law claims that directly conflict with FDA's regulatory objectives.

The Third Circuit's view that agency action "less formal" than rulemaking and adjudication cannot preempt state law, Pet. App. 12a, contradicts decisions of the Second and Fourth Circuits holding that an agency's consent order is preemptive of conflicting state law. See *Feikema* v. *Texaco, Inc.*, 16 F.3d 1408, 1415-16 (4th Cir. 1994); *General Motors Corp.* v. *Abrams*, 897 F.2d 34, 39 (2d Cir. 1990). As *Feikema* suggests, where agency action conflicts with state law, courts have often focused on "whether the agency exceeded its statutory authority or acted arbitrarily" rather than on the degree of formality of the agency's action. 16 F.3d at 1416.

B. The Third Circuit's Restrictive View Of Preemptive Agency Action Is Inconsistent With Several Lines Of This Court's Decisions

In addition to conflicting with *Dowhal* and decisions of the Second and Fourth Circuits, the Third Circuit's decision is inconsistent with this Court's cases upholding preemption in a variety of circumstances in which agencies have taken regulatory action short of formal adjudication or rulemaking. In regulating

complex aspects of the national economy, administrative agencies often employ less cumbersome means of articulating and imposing federal requirements than the time-consuming, formal proceedings required of both notice-and-comment rulemaking and agency adjudication. See, *e.g.*, 21 C.F.R. § 10.40 (requiring, with limited exceptions, a 60-day comment period for proposed FDA rules and a 30-day delay before final rules become effective). This Court has repeatedly accorded preemptive effect to regulatory activity falling outside of such formal proceedings.

The Third Circuit's position is hard to square, for example, with the "century-old" line of this Court's cases applying the "filed rate" doctrine (a species of preemption). See *American Tel. & Tel. Co.* v. *Central Office Equipment, Inc.*, 524 U.S. 214, 222, 226 (1998). As this Court has repeatedly recognized, a federal agency's certification that a filed rate is "just and reasonable" – a certification made without the strictures of either rulemaking or adjudication – suffices to preempt a state's adjustment of that rate or award of damages that would contravene the filed rate. See, *e.g.*, *Arkansas Louisiana Gas Co.* v. *Hall*, 453 U.S. 571, 576-81 (1981).

The Third Circuit's reasoning is equally difficult to reconcile with this Court's decision just last Term in *Riegel* v. *Medtronic, Inc.*, 128 S. Ct. 999 (2008). In *Riegel*, the Court concluded that the FDA's premarket approval of a medical device preempted state-law tort claims that the approved device was unsafe or defective. Premarket approval is a "rigorous process" to be sure, *id.* at 1004 (internal quotation marks omitted), but it is no more formal rulemaking or agency adjudication than is the careful and considered process in *this* case through which the FDA rejected the Martek citizen petition (after public comment), formulated and issued consumer

advisories, and issued a letter to the California Attorney General. Through these various regulatory actions, the FDA has developed and articulated a balanced and nuanced policy on the proper mercury-related warnings for fish products.

Finally, the Third Circuit's inflexible and formalistic requirement that agency action take the form of a regulation or adjudicatory decision in order to preempt state law is also at odds with this Court's recognition that an agency's decision to *forgo* regulation, at least when it implies an authoritative determination that a given area is best left unregulated, has the same preemptive effect as a decision *to* regulate. *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 66 (2002); see also *Arkansas Elec. Coop. Corp.* v. *Arkansas Public Serv. Comm'n*, 461 U.S. 375, 384 (1983). This Court has never suggested that in order to carry out a preemptive deregulatory decision, an agency must announce its decision to forgo regulation in a formal regulation. Here again, the *substance* rather than the *form* of the agency's policy is what ought to be determinative.

The approach taken by the Third Circuit also warrants review because it puts regulated entities to the untenable choice between obeying a federal agency's clear and authoritative directives under the regulatory scheme Congress entrusted to it, and obeying the contradictory requirements that a state jury may impose pursuant to state law. In this case, the FDA Commissioner has made clear that additional warning requirements imposed under state law would "frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish." FDA Preemption Letter. Moreover, the Commissioner has warned (see *ibid.*) that if petitioner and other tuna manufacturers obey those

conflicting state requirements, they will have misbranded their product under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 343. It is inconceivable that any reasonable manufacturer, under these circumstances, would ignore such a clear and direct admonition; a violation of the federal misbranding provision, after all, would trigger potential fines, imprisonment, and product seizure. See 21 U.S.C. §§ 333(a)(1), 334.

By ignoring these practical implications, the Third Circuit's analysis blinkers reality. The predictability of legal duties and obligations is critical in heavily regulated industries. This Court should provide clarity for businesses that, like the petitioner here, face state laws that directly conflict with the requirements federal agencies have clearly imposed through regulatory actions less formal than rulemaking and adjudication.

C. The Court Granted Review Of This Issue But Did Not Resolve It In *Altria* v. *Good*

In *Altria Group, Inc.* v. *Good*, 129 S. Ct. 538 (2008), this Court granted review of the First Circuit's conclusion that any FTC policy governing tar and nicotine testing and advertising could not preempt conflicting state law because the agency had "never issued a formal rule." *Good* v. *Altria Group, Inc.*, 501 F.3d 29, 51 (1st Cir. 2007). The petitioner in *Good* presented this issue for review, and cited many of the cases discussed above, including *Dowhal*, to demonstrate that the First Circuit's conclusion was contrary to the treatment of informal agency action by other courts. No. 07-562 Pet. 23.

This Court granted review in *Good*, and the parties' briefs addressed whether the agency's action was too "informal" to preempt conflicting state law. No. 07-562 Pet. Br. 51-54; No. 07-562 Resp. Br. 53-54. In the end, however, the Court's rejection of implied preemption in

Good rested on narrower grounds and left that important question unresolved. In contrast to the FDA's longstanding position in this case, the United States took the view in *Good* that the FTC had not – either formally *or* informally – authorized manufacturers to base representations that cigarette products were "light" or "low tar" on the results of FTC-required testing methods. See *Good*, 129 S. Ct. at 549 ("The Government itself disavows any policy authorizing the use of 'light' and 'low tar' descriptors."). This Court agreed that the FTC had "no longstanding policy" with which state law could conflict. *Id.* at 550. Given that conclusion, this Court had no occasion to decide whether such a policy, if it had existed, would have been drained of preemptive effect because it happened to be expressed only in "informal" agency action. See *id.* at 549.

This case presents an excellent vehicle for resolving the question left unanswered in *Good*. There can be no serious doubt that the FDA has a "longstanding policy" governing the labeling of fish products; it expressed that policy unambiguously in its Preemption Letter, in consumer advisories, and in its denial of the Martek petition. See Pet. 4-11. Indeed, the agency could hardly be clearer that the use of any warning labels that are inconsistent with the FDA's policy – including any labeling requirements imposed by state law – would "caus[e] tuna products with such warnings to be misbranded under federal law." FDA Preemption Letter. All that remains is for this Court to resolve whether such a policy, expressed in something other than a formal regulation, is capable of preempting conflicting state law. A clear resolution of that question will provide much-needed clarity for regulated entities that face the Pushme-Pullyou of unambiguous directives by federal agencies made outside of rulemaking and

adjudication that directly conflict with obligations imposed under state law.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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In The Supreme Court of the United States

TRI-UNION SEAFOODS, L.L.C.
D/B/A CHICKEN OF THE SEA,

Petitioner,

v.

DEBORAH FELLNER,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit

BRIEF OF *AMICUS CURIAE* NATIONAL FISHERIES INSTITUTE IN SUPPORT OF PETITIONER TRI-UNION SEAFOODS' PETITION FOR WRIT OF *CERTIORARI*

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TABLE OF CONTENTS

	Page
INTEREST OF *AMICUS CURIAE*	1
REASONS WHY THE PETITION SHOULD BE GRANTED	3
I. The Third Circuit Opinion Raises Important Questions That Have A Broad-Reaching Effect On The Seafood Industry And The Public Health	4
A. The FDA Has Deliberately Chosen To Rely On Advisories Instead Of Warning Labels To Educate The Public About The Benefits And Potential Risks Of Consuming Fish And Shellfish	4
B. The Third Circuit Opinion Mandates An Unworkable State Regulatory Scheme	11
C. The Third Circuit Opinion Subjects Consumers To Economic Harm, Deprives Them Of Health Benefits, And Creates Confusion	13
D. The Third Circuit Opinion Leaves The Seafood Industry Open To Conflicting Liabilities Under State And Federal Law	15
II. The Conflict Between The Third Circuit And California Supreme Court Creates Confusion About What Law Controls In Different Jurisdictions	17
CONCLUSION	18

TABLE OF AUTHORITIES

Page

CASES

Dowhal v. SmithKline Beecham Consumer Healthcare, 88 P.3d 1 (Cal. 2004).....3, 14, 15, 16, 17

STATUTES

N.J.S.A. 2A:58C-2.....9

N.J.S.A. 2A:58C-4.....10

RULES AND REGULATIONS

Cal. Code Regs., tit. 22, § 12601 .....11, 14

S. Ct. R. 10.....3, 4

FEDERAL AGENCY MATERIALS

Draft Risk and Benefit Assessment Report: Report of Quantitative Risk and Benefit Assessment of Consumption of Commercial Fish, Focusing on Fetal Neurodevelopmental Effects (Measured by Verbal Development in Children) and on Coronary Heart Disease and Stroke in the General Population (Jan. 15, 2009), http://www.cfsan.fda.gov/~dms/mehgrb.html 5, 6

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TABLE OF AUTHORITIES – Continued

Page

Letter to Martin J. Hahn, Hogan & Hartson, LLP from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA (Sept. 8, 2004), http://www.fda.gov/ohrms/dockets/dockets/03q0401/03q-0401-ans0002-vol13.pdf ..... *passim*

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INTEREST OF *AMICUS CURIAE*

The National Fisheries Institute ("NFI"), headquartered in McLean, Virginia, is a non-profit organization dedicated to educating the public about seafood safety, nutrition, and sustainability.[1] The NFI's membership consists of approximately 400 seafood producers, importers, wholesalers, retailers, grocery stores, and restaurant chains, including companies such as Bumble Bee Foods, StarKist, Gorton's, Darden Restaurants, and Long John Silver's. The NFI promotes adherence to the Dietary Guidelines for Americans jointly issued by the Department of Health and Human Services and Department of Agriculture that suggest that Americans should eat fish and shellfish twice per week to reduce the risk of mortality from coronary heart disease. Among the most popular seafood items that the NFI's members catch, grow, process, distribute, and sell are tuna, shrimp, catfish, salmon, crab, and tilapia. Thus, its members have a vital interest in ensuring that the distribution of healthy and nutritious seafood to consumers is not hampered by state regulations that

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[1] Tri-Union, the petitioner in this action, is one of several hundred members of the NFI, as is a sister corporation, Empress International Ltd. This *amicus* brief was funded entirely by the NFI out of its regular operating funds. No additional funds were contributed by Tri-Union or any other person or entity for the purpose of preparing this *amicus* brief. The NFI requested and received written consent to the filing of this brief of *amicus curiae*, as reflected in the concurrently filed letters from petitioners' and respondents' counsel.

impose complex, confusing, inconsistent, and potentially illegal warning label obligations that interfere with the carefully considered approach to seafood health and safety that the Food and Drug Administration has developed over the course of the past two decades.

The fish and shellfish industry is a major contributor to the United States economy. According to a 2008 report from the National Marine Fisheries Service ("NMFS"), "[b]y producing and marketing a variety of fishery products for domestic and foreign markets, the commercial marine fishing industry contributed $34.2 billion (in value added) to the U.S. Gross National Product." NMFS, Fisheries of the United States 2007 (July 2008), http://www.st.nmfs.noaa.gov/st1/fus/fus07/fus_2007.pdf, at v. Domestic consumers spent $68.4 billion on seafood in 2007, consuming a *per capita* average of 16.3 pounds of fish and shellfish in that year. *Id.* at iv-v.

The NFI submits this *amicus* brief in support of Tri-Union's Petition because the practical effect of the Third Circuit's opinion is to impose a nearly impossible compliance burden on thousands of domestic seafood producers and sellers. Specifically, to avoid the possibility of incurring significant liability for damages in private state actions, they must place methylmercury warning labels on virtually all of their fish and shellfish products, not just their tuna products, because those products all contain some amount of methylmercury. The Third Circuit would require these warnings even though the FDA has

stated that they are inherently incapable of providing the sophisticated and nuanced advice that the agency has developed over the years through a series of advisories issued under the federal Food, Drug and Cosmetics Act ("FDCA"). The opinion also subjects seafood sellers to great uncertainty and huge potential expense if they must comply with widely varying state laws governing what seafood sellers should and should not say in warnings about methylmercury levels.

REASONS WHY THE PETITION SHOULD BE GRANTED

Tri-Union's Petition identifies two separate grounds for *certiorari*: (1) the Third Circuit opinion raises an important question of federal law that this Court should settle, namely, whether the FDA's deliberate decision not to require consumer warnings for methylmercury in seafood should be given pre-emptive effect to avoid the chaos and burden that would result from inconsistent and conflicting state law warning label requirements; and (2) the opinion directly conflicts with the opinion of the California Supreme Court in *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1 (Cal. 2004), which held that the FDCA would preempt state law warning requirements like the ones that seafood suppliers would have to adopt to avoid liability under the New Jersey laws discussed in the Third Circuit opinion. S. Ct. R. 10(c) (the Court considers whether "a United States court of appeals has decided an important

question of federal law that has not been, but should be, settled by this Court"); S. Ct. R. 10(a) (the Court considers whether a United States court of appeals "has decided an important federal question in a way that conflicts with a decision by a state court of last resort"). *Certiorari* should be granted to settle the law, which has grave ramifications for the seafood industry as well as for consumer health, and to resolve the conflict.

I. The Third Circuit Opinion Raises Important Questions That Have A Broad-Reaching Effect On The Seafood Industry And The Public Health.

A. The FDA Has Deliberately Chosen To Rely On Advisories Instead Of Warning Labels To Educate The Public About The Benefits And Potential Risks Of Consuming Fish And Shellfish.

The benefits of eating fish and shellfish are well-established. In its most recent consumer advisory, entitled *What You Need to Know About Mercury in Fish and Shellfish*, 2004 EPA-823-R-04-005 (March 2004), http://www.cfsan.fda.gov/~dms/admehg3.html ("2004 Advisory"), the FDA summarized these important benefits as follows:

> Fish and shellfish are an important part of a healthy diet. Fish and shellfish contain high-quality protein and other essential nutrients, are low in saturated fat, and contain omega-3 fatty acids. A well-balanced diet that

> includes a variety of fish and shellfish can contribute to heart health and children's proper growth and development. So, women and young children in particular should include fish or shellfish in their diets due to the many nutritional benefits.

In addition, the FDA has just published a draft report that reinforces the 2004 Advisory:

> Fish provides protein, is low in saturated fat, and is rich in many micronutrients; it also can be a source of certain omega-3 fatty acids. As the Institute of Medicine of the National Academies of Science (IOM) noted in a recent report, "[i]n the past several years, research has implicated seafood, particularly its contribution of EPA and DHA [two omega-3 fatty acids], in various health benefits identified for the developing fetus and infants, and also for adults, including those at risk for cardiovascular disease" (IOM 2006 at 1).

Draft Risk and Benefit Assessment Report: Report of Quantitative Risk and Benefit Assessment of Consumption of Commercial Fish, Focusing on Fetal Neurodevelopmental Effects (Measured by Verbal Development in Children) and on Coronary Heart Disease and Stroke in the General Population (Jan. 15, 2009), http://www.cfsan.fda.gov/~dms/mehgrb.html ("2009 Draft Report").

Although the FDA recognizes the potential risk of excessive methylmercury consumption by pregnant

women, women who intend to become pregnant, nursing mothers, and young children, the FDA nonetheless concludes that "consumption of fish species that are low in methylmercury has a significantly greater probability of resulting in a net benefit, as measured by verbal development [in children]." 2009 Draft Report at 3. Moreover, "[f]or fatal coronary heart disease and stroke, commercial fish baseline consumption is averting a central estimate of over 30,000 deaths per year from coronary heart disease and over 20,000 deaths per year from stroke." *Id.*

To address the risks to those consumers that could possibly develop health problems due to high levels of methylmercury exposure, the FDA has issued targeted advisories that provide specific information about the types of fish and shellfish that are safe to eat and those that should be avoided. Letter to Martin J. Hahn, Hogan & Hartson, LLP from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA (Sept. 8, 2004), http://www.fda.gov/ohrms/dockets/dockets/03q0401/03q-0401-ans0002-vol13.pdf at 28, n.71 ("FDA Martek Petition Denial") (describing targeting mailings from the FDA to obstetricians and gynecologists, as well as efforts to use women's magazines and professional health organizations to spread information to the target populations). These advisories educate consumers about the amounts of different types of seafood that are safe for consumption. *See, e.g.*, 2004 Advisory. The FDA has concluded that these advisories are the best way to educate the public and protect those most at

potential risk of developing methylmercury-related health problems, while also ensuring that the public is not deterred from consuming fish and shellfish. FDA Martek Petition Denial at 28-29.

The FDA deliberately decided to rely on advisories and communications through physician's offices, and not to require product warnings about methylmercury to be placed: (1) on every package of tuna and other mercury-containing seafood; (2) at every grocery store fish counter; and (3) on every restaurant menu. In rejecting a petition seeking to impose point of sale product-specific methylmercury warnings, the FDA explained that they do not and cannot contain the "level of clarity and detail" necessary to explain the types of seafood that people should and should not eat, and their appropriate serving sizes, because there is insufficient space on a product label. FDA Martek Petition Denial at 29. The FDA further warned of confusion "when different kinds of label statements are put on different species of commercial fish and not on locally caught fish." *Id.*

In addition, the FDA recognized that warnings might deter consumers outside the at-risk groups from eating any seafood, which would result in loss of the significant health benefits associated with seafood consumption:

> [A] label statement that reaches the public at large can also have unintended adverse public health consequences. FDA focus group results suggest that people who are not in the target audience (*i.e.*, women who are not

> nursing and not likely to become pregnant, and men) might eat less fish or refrain from eating fish altogether when they receive information about the mercury content of fish and possible harmful health effects to pregnant women, women who might become pregnant, nursing mothers, and young children (ORC Macro, 2003). Therefore, the statement about possible harmful effects of mercury accompanying the qualified health claim would likely have the effect of negating the qualified health claim.

FDA Martek Petition Denial at 29. Thus, the FDA has selected detailed advisories instead of necessarily abbreviated point of sale product-specific warning labels as the appropriate method of balancing the health benefits of fish and shellfish consumption with the possible risks of exposure to methylmercury. The FDA also has chosen to distribute the advisory through physicians, who are well-suited to communicate the nuanced messages. By rejecting federal preemption of state regulation, the Third Circuit upsets this carefully tailored health and safety policy.

B. The Third Circuit Opinion Mandates An Unworkable State Regulatory Scheme.

The Third Circuit opinion affects virtually the entire fish and shellfish industry, not just sellers of canned, pouched, frozen, and fresh tuna. The 2004 Advisory states that "nearly all fish and shellfish contain traces of mercury." Consequently, every seller

of fish and shellfish is potentially subject to a product liability lawsuit under broadly written state statutes when they fail to warn in some way all consumers, not just the groups that the FDA has determined are potentially at risk, about the possible risks of consuming fish or shellfish that contain at least trace elements of methylmercury.

The New Jersey law at issue in this case illustrates the difficulty that seafood suppliers face in attempting to devise "adequate warnings" for all of their products. It states that a manufacturer or seller of a product:

> shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: . . . b. failed to contain adequate warnings or instructions.

N.J.S.A. 2A:58C-2. The statute does not define what constitutes an "adequate warning," but instead provides that:

> [a]n adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the

> persons by whom the product is intended to be used.

N.J.S.A. 2A:58C-4.

Under this statute, nearly every seafood product would require some form of methylmercury warning label or sign on its container or at the point of sale to the consumer, but the type of warning would necessarily need to vary depending on the type of product, the amount of that product being purchased at one time, as well as over time, and the demographic profile of the potential purchaser.

The Third Circuit did not recognize the complexity of New Jersey's "adequate warning" requirement. It stated that Tri-Union could have avoided liability by including a warning that "specified that the risks become material only with frequent tuna consumption, and that moderate fish consumption offers positive health benefits." Appendix to Tri-Union Petition ("App.") at 35a. However, every seafood seller – not just distributors like Tri-Union, but also, for example, grocery store chains, stand-alone fish markets, and restaurants – would need to devise warnings tailored to the type of methylmercury-containing seafood being sold. In other words, a warning for one seafood product with a negligible methylmercury content would not be "adequate" to warn of the potential risks of over-consumption of another seafood product with a relatively high

methylmercury content.[2] And, if the stronger warning was used for all seafood products, then consumers would respond by reducing their purchases of those products with negligible methylmercury content, thereby depriving themselves of the strong health benefits about which the FDA has advised consumers in its advisories.

That would just be for New Jersey. Other states have enacted product liability laws that take different positions on what constitutes an adequate consumer warning. California, for instance, contains an optional "safe harbor" provision that allows a seafood supplier to use a generic warning to comply with the state warning law requirement: "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm." Cal. Code Regs., tit. 22, § 12601(b)(4)(B). It is

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[2] This would even be true for different types of canned tuna, because, as the FDA has acknowledged, canned light tuna has a lower methylmercury content than white albacore tuna. *See* 2004 Advisory (listing "canned light tuna" as a low-mercury product, but recommending restricting consumption of white albacore tuna to no more than 6 oz. per week because it "has more mercury than canned light tuna."). Thus, if seafood suppliers must provide warnings specific to different seafood products to comply with state warning law requirements, a warning applicable to canned light tuna would not be sufficient to warn of the risks of overconsumption of canned white albacore tuna. Thus, the products would require different warnings. Alternatively, a single warning covering both types of tuna would discourage greater consumption of light tuna even though the FDA has found that greater consumption of it does not create a health risk.

difficult to see how such a warning would "communicate[ ] adequate information on the dangers and safe use of the product," as required by the New Jersey statutes, or "specif[y] that the risks become material only with frequent tuna consumption," as the Third Circuit suggested would avoid a products liability claim. This would mean that what is appropriate for California may not suffice in other states.

In summary, the Third Circuit opinion upends the careful work of the FDA by requiring the seafood industry to develop warning labels and point of sale signs for all seafood products that contain any amount of methylmercury, no matter how small, to avoid the risk of a product liability lawsuit by a consumer like Deborah Fellner, who overindulges in disregard of both common sense and the FDA's widely circulated advisories.[3] Moreover, varying state warning label requirements will require multi-state seafood suppliers to adopt a state-by-state approach to compliance, which will impose an impossible burden. In contrast, the FDA's considered analysis of scientific data and its decision about how best to protect the public will be ignored. The resulting unworkable scheme of state government regulation will substantially harm the seafood industry, making compliance with warning laws extremely difficult and driving up the costs of providing fish and shellfish to the public.

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[3] As the Third Circuit noted, "from 1999 to 2004, [Ms. Fellner's] diet consisted almost exclusively of TriUnion's tuna products." App. at 2a.

C. The Third Circuit Opinion Subjects Consumers To Economic Harm, Deprives Them Of Health Benefits, And Creates Confusion.

The seafood industry is not alone in facing increased economic costs because of the Third Circuit's opinion. If the industry is forced to incur significant expenses to provide state-by-state warnings, some of those costs will be passed on to consumers. That could drive up the cost of seafood, which will, in turn, result in decreased consumption, along with the loss of the health benefits associated with their consumption.

Consumer confusion is another serious danger. If seafood sellers are forced to place detailed product-specific warnings on their packages, as well as at grocery store fish counters and on restaurant menus, they are likely to confuse consumers and decrease overall seafood consumption. As the FDA's focus groups demonstrated, general warnings about methylmercury deter beneficial consumption by the general public, not just the groups that are potentially at risk of methylmercury-related health problems.[4] FDA Martek Petition Denial at 28. That will adversely affect the public health, which is precisely

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[4] An equal concern is that the groups for whom the FDA has issued targeted warnings – pregnant women, nursing mothers, and young children – may be overwhelmed by warnings and may disregard them altogether.

what the FDA sought to avoid by relying on advisories instead of warning labels.

The California "safe harbor" warning illustrates how general warnings may be counter-productive. It allows a seller to comply with the warning requirement merely by stating that a product "contains a chemical known . . . to cause birth defects or other reproductive harm." Cal. Code Regs., tit. 22, § 12601(b)(4)(B). Since all fish and shellfish contain some amount of methylmercury, a grocery store, for instance, might be able to satisfy its warning obligations by placing a single "safe harbor" warning on its seafood display case. But that would not provide information to consumers about the relative benefits and potential risks of seafood for different groups of consumers, or draw distinctions between the types of seafood that are safe for the at-risk groups to consume and those they should avoid. Instead, such a warning is likely to deter consumers from buying any seafood.

That is precisely why the California Supreme Court held the FDCA preempted California's warning law as it applied to nicotine-containing products designed to help people stop smoking. Although the "safe harbor" warning was arguably true for the smoking-cessation products, a general warning "may mislead the consumer into misjudging the dangers stemming from use of the product, and consequently making a medically unwise decision." *Dowhal*, 88 P.3d at 14. Thus, for example, the "safe harbor" warning may deter a pregnant woman from using the

smoking-cessation product, and instead continue smoking, despite its greater health risks. *Id.*

By the same logic, general warnings could deter people from consuming any seafood. While well-intended, state law warning requirements could actually hurt the public and should be preempted when the FDA has chosen instead to use a "nuanced" approach to balancing the benefits and risks of certain products (*Dowhal*, 88 P.3d at 15). Thus, allowing the Third Circuit opinion to stand unreviewed could have grave implications for the public health.

D. The Third Circuit Opinion Leaves The Seafood Industry Open To Conflicting Liabilities Under State And Federal Law.

The FDA Martek Petition Denial also highlights another significant danger of warnings – they may provide false information. Sellers of fish and shellfish may adopt unnecessary warnings simply to avoid the prospect of litigation. For instance, the Martek Petition requested that the FDA issue a statement that mercury counteracts the beneficial effects of EPA and DHA omega-fatty acids on cardiovascular health, but the FDA rejected the request because the scientific evidence on the subject was inconclusive. FDA Martek Petition Denial at 29. The FDA, however, does not face the prospect of ruinous lawsuits over failure to warn. Seafood suppliers, on the other hand, do face such potential lawsuits and would likely place

warnings about specific risks from consuming fish and shellfish that are not supported by science, but could be asserted in defense of future lawsuits. False or unsubstantiated warnings will only further deter fish consumption.

This places the seafood industry in an untenable position. As discussed in Tri-Union's Petition (at 22-26), Section 403 of the FDCA prohibits "misbranding," the furnishing of false and misleading information. The FDA has previously taken the position that the warnings required by California statute violate the FDCA. App. at 32a-34a (discussing letter from FDA Commissioner to California Attorney General); Tri-Union Petition at 22-24 (discussing same); *see also* Letter to Bill Lockyer, Attorney General of the State of California, from Lester M. Crawford, Commissioner of Food and Drugs dated Aug. 12, 2005, http://www.cfsan.fda.gov/~dms/fl-ltr65.html. Thus, complying with state warning requirements to avoid product liability actions could place seafood suppliers in an intractable conflict. They would face liability for not issuing warnings under state law, but potential action by the FDA for misbranding if they do issue warnings.

The Third Circuit dismissed this risk by stating that the FDA has taken no action against fish or shellfish sellers for misbranding. App. at 33a-35a. That conclusion ignores the obvious: until the Third Circuit opinion, seafood sellers did not face significant exposure from private lawsuits due to an alleged failure to warn, and *Dowhal*, which addressed similar

issues, had held that the FDA's decision to rely on advisories preempted state law warnings. Moreover, as the Third Circuit acknowledged, the FDA had issued a letter to the California Attorney General opining that state-law warnings about tuna would constitute false and misleading statements in violation of the FDCA. App. at 32a-34a. The FDA's position is clear that seafood producers and sellers face conflicting obligations if they try to comply with both state and federal law.

This Court can resolve the conflict by deciding whether the FDCA preempts state law and if compliance with state warning requirements would constitute "misbranding." Absent a grant of Tri-Union's Petition, the entire American seafood industry will be placed in the untenable position of choosing which liability – state or federal – they would prefer to incur. To avoid such an unworkable result, this Court should grant *certiorari*.

II. The Conflict Between The Third Circuit And California Supreme Court Creates Confusion About What Law Controls In Different Jurisdictions.

Tri-Union's Petition fully details the direct conflict that exists between the Third Circuit opinion and the California Supreme Court's opinion in *Dowhal*. The NFI will not repeat the specifics of this conflict, but the implications for the seafood industry are enormous.

Absent review, in some parts of the country, *e.g.*, California, state-law warnings have been declared preempted by the FDCA. Within the Third Circuit, however, state law warnings and product liability lawsuits based on failure to warn may be pursued. In the rest of the country, which law controls is unsettled. This will force seafood suppliers to litigate the preemptive effect of the FDCA in multiple jurisdictions, which is an unnecessary waste of judicial and the industry's resources, time, and money that could be avoided by a grant of *certiorari*.

CONCLUSION

For all of these reasons, and those discussed more fully in Tri-Union's Petition, the Third Circuit's opinion requires review by this Court. Given the significant risks the Third Circuit's opinion creates for the public health, and the tremendous burden it creates for the seafood industry, the Court should grant Tri-Union's Petition for a Writ of *Certiorari*.

Respectfully submitted,

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